Supreme Court, U.S.
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No.

IN THE
Supreme Court of the United States

ASTELLAS PHARMA, INC.

Petitioner,

v.

LUPIN LIMITED and
LUPIN PHARMACEUTICALS, INC.

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit erred in ignoring the Court's binding precedent and finding product-by-process claims are not infringed by an identical product made by a different process?

PARTIES TO THE PROCEEDINGS AND CORPORATE DISCLOSURE STATEMENT

The parties to this proceeding are: Petitioner/Appellant Astellas Pharma, Inc. and Respondents/ Appellees Lupin Ltd. and Lupin Pharmaceuticals, Inc. Although Abbott Laboratories was an appellant below, it has not joined in this petition for *certiorari*.

The Federal Circuit's decision in 2007-1446 (this case) was a final decision disposing of all issues between the parties. On appeal, the Federal Circuit heard this case with 2007-1400, which involved the same patent and the same plaintiffs. That case was an appeal of a denial of a preliminary injunction to plaintiffs Astellas Pharma, Inc. and Abbott Laboratories and against defendants Sandoz, Inc., Sandoz GMBH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical. After remand, that case is currently stayed pending the outcome of this petition for *certiorari*. Astellas has provided a courtesy copy of this petition to the defendants in that case.

As required by the Court's Rule 29.6, Astellas Pharma, Inc. states that there is no parent corporation and no publicly held company owns 10% or more of its stock.

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PETITION FOR *CERTIORARI*

Petitioner Astellas Pharma, Inc. ("Astellas") respectfully seeks a writ of *certiorari* to the United States Court of Appeals for the Federal Circuit.

OPINION BELOW

The judgment of the Federal Circuit (en banc as to Section III(A)(2)) was entered on May 18, 2009. Due to an extension granted by the Chief Justice, this petition is due by September 16, 2009. The opinion of the court of appeals was reported at *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009). App. 1-88. The opinion of the district court granting summary judgment was entered on June 14, 2007 and was reported at *Lupin Ltd. v. Abbott Labs.*, 491 F. Supp. 2d 563 (E.D. Va. 2007). App. 89-103.

JURISDICTION

The judgment of the court of appeals, en banc as to Section III(A)(2), was entered on May 18, 2009. App. 1. On July 24, 2009, in Application 09A97, the Chief Justice extended the time to file the petition for *certiorari* until September 16, 2009. The jurisdiction of the Court is invoked under 28 U.S.C. § 1254(1). The jurisdiction of the Federal Circuit was invoked under 28 U.S.C. § 1295(a)(1).

CONSTITUTIONAL PROVISION INVOLVED

The United States Constitution, Art. I, Sec. 8, states that "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by

securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

STATEMENT OF THE CASE

I. Introduction

This case is without precedent. Here, the Federal Circuit *sua sponte* and over dissenting opinions went en banc and decided an important patent law issue with no notice to the public. In deciding that product-by-process "claims are treated as process claims for infringement," App. 81 (Newman, J., dissenting), the Federal Circuit devalued thousands of active patent claims and overturned 110 years of direct precedent that held that product-by-process claims do cover the product, regardless of how made. Worse still, the Federal Circuit violated the Court's precedent, which requires claims to be interpreted the same way for both infringement and invalidity. As the Court held 120 years ago, "[t]hat which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (U.S. 1889) (internal quotations omitted). The holding put forward by the en banc court here violates that rule, in that now a product described in a product-by-process claim will anticipate if earlier (even if the process used to create it is different from the process in the claim), but will *not* infringe if later (if the process used to create it is different from the process in the claim). Accordingly, the Court should grant the petition for *certiorari* and decide if it was proper for the Federal

Circuit to decide that this Court's binding precedent does not apply to an entire class of claims.

"In a product-by-process claim, a product is protected, even though the product is described by the process that produces it." Mark D. Passler, Comment, *Product-By-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act*, 49 U. Miami L. Rev. 233, 234 (Fall, 1994). By no later than 1891, the United States Patent Office had officially recognized that a product may be claimed by the process that makes that product (a "product-by-process" claim). *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891). Nevertheless, the Federal Circuit ignored that precedent, along with the Court's precedent, and decided to take away an inventor's right to claim a product by the process that makes that product (unless the product is made by the exact process described). In addition, its decision to go en banc with no notice to the public that it was overturning its own precedent on this issue violated its own procedural rules by not giving interested third parties a chance to comment. Thus, third parties lost the opportunity to demonstrate that product-by-process claims are even more important in the 21st century than they were in the 19th century, when they were first allowed.

II. Proceedings Below

Astellas is the assignee of U.S. Patent No. 4,935,507 ("the '507 patent"). The claims of the '507 patent are directed to certain crystalline forms of a compound known generically as cefdinir.

On June 14, 2007, the United States District Court for the Eastern District of Virginia granted summary judgment of non-infringement to Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"). The bases for that court's jurisdiction were 28 U.S.C. §§ 1331 and 1338.

The lower court found that Lupin did not infringe claims 2-5 (the only claims at issue) because Astellas did not present evidence that Lupin's product was made by practicing the processes set forth in claims 2-5. App. 96, 101-102. The lower court based its holding on *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), which held that a product-by-process claim is only infringed by a product that is made by the process described in the claim. *Id.* at 846-47. In so ruling, the *Atlantic* panel attempted to overrule *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), which had held just one year previously that a product-by-process claim is infringed by a product that is the same as the product described in the product-by-process claim, regardless of the process used to make the product. *Id.* at 1583.

Astellas appealed the lower court's decision to the Federal Circuit, which *sua sponte* went en banc to decide the product-by-process issue and then affirmed the lower court's decision. The one thing that may be said about the Federal Circuit's en banc decision is that it finally resolved the intra-circuit split between *Scripps* and *Atlantic*. With conflicting precedent, some district courts correctly followed

Scripps, *see, e.g., Trs. of Columbia University v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16, 31-32 (D. Mass. 2000); *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 2002 U.S. Dist. LEXIS 25275, *16 (E.D. Pa., Dec. 20, 2002); *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 372 F. Supp. 2d 430, 436 (D. N.J. 2005); *Mannington Mills, Inc. v. Armstrong World Indus., Inc*, 218 F. Supp. 2d 594, 600 (D. Del. 2002); and some district courts (such as the one in this case) incorrectly followed *Atlantic*. *See, e.g., Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7, 10 (D. Mass. 1993). The reason it was correct for the district courts to follow *Scripps* and incorrect for the district courts to follow *Atlantic* is not because *Scripps* was correctly decided and *Atlantic* was incorrectly decided (although they were), but rather because the Federal Circuit follows the well-established rule that "[w]here there is a direct conflict [between decisions of the Federal Circuit], the precedential decision is the first." *Yunus v. Dept. of Veterans Affairs*, 242 F.3d 1367, 1372 n.2 (Fed. Cir. 2001) (internal quotation omitted). Thus, unless and until overturned by the en banc Federal Circuit, *Scripps* remained "good law." *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988) ("prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned en banc").

Now, of course, due to the Federal Circuit's *sua sponte* decision to go en banc and overturn *Scripps*, that case is no longer "good law." But, as the dissent noted, before overturning 110 years of precedent, at the very least, the Federal Circuit should have followed its own procedures and

publicized the fact that it was considering whether to change the law on product-by-process claims. But it failed to do so. Accordingly, numerous patent holders, including pharmaceutical and biological companies, were precluded from explaining why it is critical to their industries that product-by-process claims cover the product described and not the process used to make that product.

The law is now very clear that a product-by-process claim no longer covers the product, unless that product was made by the process described in the claim. Because the Federal Circuit has spoken clearly on this issue, it would not be proper for a party to even raise in a district court that a product-by-process claim covers a product made by a different process. *See* Fed. R. Civ. P. 11(b)(2). At most, a party could raise this argument before the district court and explain that, while the district court must follow precedent, the party is reserving the issue so that it can ask the Federal Circuit to go en banc again to reconsider the issue it just decided here, or seek a writ of *certiorari* to the Court regarding this issue. *Cf. Gomez-Astorga v. United States*, 2008 U.S. Dist. LEXIS 15808, *7 (D. Utah Feb. 29, 2008) (where issue was "foreclosed by clear precedent," the appeal was brought "only to preserve the issue on *certiorari* to the United States Supreme Court"). But considering that the Federal Circuit just decided this issue en banc, after letting the clear intra-circuit split fester on this issue for over 17 years, there is virtually no chance that the Federal Circuit would rehear this issue any time in the foreseeable future.

Finally, because the Federal Circuit has turned product-by-process claims into virtually pure process claims (albeit with an additional hurdle to cross because for patentability the patentee must prove the product is new, while for infringement purposes the relevant consideration is the process), there will be little point in patentees seeking product-by-process claims. Therefore, there will likely be few product-by-process claims for any court to review after the current product-by-process claims all expire within the next twenty years. Thus, for all practical purposes, this case will be the last chance for this Court to decide (and the public to comment on) whether the Federal Circuit properly overturned 110 years of precedent to turn product-by-process claims into little more than process claims.[1]

REASONS FOR GRANTING THE PETITION

Judge Newman, the author of *Scripps*, had some very specific criticisms of the majority opinion, which was written by Judge Rader, the author of *Atlantic*. These criticisms were in five main categories. As each of Judge Newman's criticisms

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[1] In addition, there would be no advantage for the Court to wait to decide this issue in some future case because 1) as the en banc court has clearly spoken on this issue, there should be little or no change to the law of product-by-process claims going forward, and 2) as the district court and a Federal Circuit panel will have no choice but to hold that product-by-process claims do not cover the product, there will probably be much less briefing and discussion on this issue in any future case (assuming *arguendo*, that there is even a future case that addresses this issue).

are correct, the Court should grant this petition and review the Federal Circuit's en banc opinion.[2]

I. By Failing to Follow Its Own Procedures, the En Banc Majority Took Away an Entire Class of Patents without Receiving Any Input from the Public

Judge Newman's first criticism was the Federal Circuit's failure to follow its own procedures for hearing cases en banc. According to Petitioner's research, in the last twenty years, it appears that the Federal Circuit has decided cases en banc approximately sixty times, about three times per year. En banc cases are heard so infrequently because such cases are reserved for only "question[s] of exceptional importance." Fed. R. App. P. 35(a)(2). Because these cases are so important, the Federal Circuit's Internal Operating Procedures ("IOP") require the court to tell the public the issues it is deciding en banc so that the public may file amicus briefs regarding those issues. IOP 14.3(c).

There appear to be two reasons why the Federal Circuit Internal Operating Procedures require notice to the public. First, as in this case, decisions by the en banc court may affect thousands of currently issued patents, and thus members of the public who could be affected by those decisions should be allowed to comment before any rules change. Second, decisions by the en banc court as they relate to patent law are generally final, due to

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[2] In addition, as discussed *infra* in section VI, there are important public policy reasons for granting the petition.

the Federal Circuit's exclusive appellate jurisdiction over patent law. Indeed, in the last twenty years, it appears that this Court has granted a petition for *certiorari* from an en banc holding of the Federal Circuit only eight times.

Consequently, the Federal Circuit virtually always announces when it is going to rule en banc to give the public a chance to comment on the issue the Federal Circuit is considering. It is true, however, that its internal operating procedures state that the Federal Circuit is not bound by those procedures. IOP 1. It is also true that this is not the first case where the Federal Circuit *sua sponte* and without notice to the public decided a case related to patent law en banc. Petitioner's research appears to show that there have been two such cases out of the approximately sixty cases decided en banc by the Federal Circuit in the last twenty years.[3] Those cases are *Midwest Industries, Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999) (en banc in part, *overruled on other grounds*), and *DSU Medical Corp. v. JMS Co., Ltd.*, 471 F.3d 1293 (Fed. Cir. 2006) (en banc in part). In both cases, there was not a single dissent. Thus, with unanimity on that court, briefs from the public would probably have been an exercise in futility.

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[3] In the last twenty years there also have been a few other cases not related to patent law where it appears that the Federal Circuit *sua sponte* decided cases en banc without previous notice to the public. *See, e.g., In re Violation of Rule 50*, 78 F.3d 574 (Fed. Cir. 1996) (en banc) (deciding, over one dissenter, whether a former law clerk improperly practiced before the Federal Circuit).

Moreover, the issues decided en banc in those cases did not involve a ruling that would virtually invalidate an entire class of patent claims. In *Midwest*, the Federal Circuit decided the limited question that it would use its own law "in resolving questions involving the relationship between patent law and other federal and state law rights." *Midwest*, 175 F.3d at 1358-59. In *DSU*, the Federal Circuit merely clarified that to prove inducement of infringement "[t]he plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." *DSU*, 471 F.3d at 1304.

Thus, there appears to have been exactly *one case* (this case) where the Federal Circuit *sua sponte* decided an important issue of patent law over dissenting judges and did not give the public a chance to brief the issue. Such a procedure, in violation of its own rules, especially in a case where it made thousands of patent claims virtually worthless, was improper. The Court should grant the petition and hear this case so that the holders of those now virtually worthless patent claims will have a chance to comment on this issue.

In addition, not only was the public at large precluded from commenting on this issue, but so was Petitioner. In its briefing to the Federal Circuit, Astellas' main focus was not on whether *Atlantic* was correctly decided because *Scripps* remained "good law." Instead, Astellas focused its main argument on the fact that *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), "sets forth

the proper analysis for interpretation of *all* claims, without making any special exception for product-by-process claims and, thus, there was never any need to choose between *Scripps* and *Atlantic*." Astellas Opening Brief at 3 (emphasis in original).

If the Federal Circuit had followed its own procedures and informed Astellas that it was deciding this issue en banc, Astellas would have never stated that "there was never any need to choose between *Scripps* and *Atlantic*" because obviously the new en banc opinion would, in fact, "choose between *Scripps* and *Atlantic*." Therefore, because the Federal Circuit failed to follow its own procedures, Astellas lost its right to focus its argument on why the en banc court should follow *Scripps* and not *Atlantic*.

II. The En Banc Majority Erred in Deciding that Product-by-Process Claims Are to Be Interpreted Differently for Validity than for Infringement

The most important error in the majority's analysis is the fact that claims are now interpreted differently for validity purposes than for infringement purposes. As Judge Newman explained, a product-by-process claim is now a *product claim* when the Patent Office is deciding whether it is patentable, and is "subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made." App. 82. But a product-by-process claim is now a "*process claim*[ ] for infringement." *Id.* 82 (emphasis added). Thus,

"[f]or the first time, claims are construed differently for validity and for infringement." *Id.* at 81.

It is one of the oldest maxims in patent law, however, that claims are to be interpreted the same for infringement as for validity. As the Court explained 120 years ago: "That which infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg. Co.*, 129 U.S. 530, 537 (U.S. 1889) (internal quotations omitted). This maxim has been followed repeatedly by the Federal Circuit. *See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("claims are construed the same way for both invalidity and infringement"); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses"); *see also* Donald S. Chisum, *5A Chisum on Patents §18.01* (2007) ("A fundamental tenet of patent law is that a claim must be interpreted consistently for purposes of infringement and validity"). Indeed, one law professor commenting on the majority opinion stated that "[i]t doesn't make sense to have the same claim language mean different things for infringement and validity purposes." Steven Seidenberg, *Process Perils: Ruling Narrows the Protection for Product-by-Process Patents*, Inside Counsel at 23 (Aug. 2009) ("*Process Perils*") (quoting University of Michigan Law professor, Rebecca Eisenberg).

Judge Rader's majority opinion ignores the dissent's argument. But, in his original *Atlantic* opinion, Judge Rader freely admitted that the

Federal Circuit's new rule led to one claim interpretation for validity and another for infringement when he stated that "even though product-by-process claims are limited by and defined by the *process* [for infringement], determination of patentability [validity] is based on the *product* itself." *Atlantic*, 970 F.2d at 845 (emphasis added). He further expounded on this issue in his concurrence to the denial of rehearing en banc in *Atlantic* when he stated that the Supreme Court cases he discussed were not limited to old products because "[i]n its infringement rule, the [Supreme] Court did not presume to address patentability concerns like those in *35 U.S.C. §§ 102* [anticipation], *103* [obviousness]." *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1299, 1303 (Fed. Cir. 1992) (Rader, J., concurring) ("*Atlantic Concurrence*"). That is an incorrect statement of patent law.

The Court does not treat infringement separate from anticipation and obviousness. As the Court held, "[t]hat which infringes, if later, would anticipate, if earlier." *Peters*, 129 U.S. at 537. The majority's new standard for product-by-process claims violates that binding precedent. Now, a product that "anticipate[s], if earlier" because it is the same product described by the product-by-process claims *does not* "infringe if later," if it is made by a different process.[4] Thus, the majority's

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[4] Based on a statutory change, the "classic test" put forth in *Peters* has now changed slightly. The Federal Circuit has explained that the "'classic test' must be modified to: That which would *literally* infringe if later in time anticipates if earlier than the date of invention." *Lewmar Marine, Inc. v.*

new rule for product-by-process claims can lead to absurd results. For example, in some cases, juries must decide whether a defendant's product was made (regardless of the process used) before the critical date of a patent. Under the Court's binding precedent, if the jury decides the product was made before, it anticipates; and if the product was made after, it infringes.[5] But that simple rule has been turned on its head by the rule put forward by the en banc majority. Now, if the product was made by a different process than claimed in the patent, and the jury found the product was made before the critical date, it must also find that the product *anticipates* the patented claim. On the other hand, if the jury found the product was made after the critical date, it must also find that the product *does not infringe* the product-by-process claim.

Long ago, the Court explained that a patent claim is not "a nose of wax which may be turned and twisted in any direction," to be interpreted different ways. *White v. Dunbar*, 119 U.S. 47, 51 (U.S. 1886). Here, the majority opinion renders a patent claim as "a nose of wax," twisting and turning the language of the claim to give it one meaning for infringement and an entirely different meaning for validity. Thus,

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Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added).

[5] This example assumes that the patentee conceived of the invention by the critical date and diligently worked on reducing the invention to practice. *Cf.* 37 C.F.R. § 1.131 (discussing prerequisites for swearing behind a reference that is less than one year before the priority date).

Professor Eisenberg stated that the majority's decision here will not "fly in the long run" due to the fact that claim language now "mean[s] different things for infringement and validity purposes." *Process Perils* at 23. But unfortunately the decision of the en banc court will "fly in the long run" unless the Court grants this petition for *certiorari*. Consequently, the Court should grant the petition for *certiorari* to decide whether it was proper for the Federal Circuit to contradict its binding precedent with its new product-by-process rule.

III. The En Banc Majority Erred in Deciding that There Should Be a Single Rule for Product-by-Process Claims Regardless of Whether the Product Claimed Was Old or New

Judge Newman explained that this Court's precedent firmly recognized "that when the product was old and only the process was a patentable invention, a claim for the 'product of that process' could not cover the old product made by a different process." App. 65. She noted, however, that the majority opinion ignored the difference between old products and new products. *See id.* at 53-54, 67.

Although the majority opinion was also silent on this issue, Judge Rader did address this exact issue in his *Atlantic Concurrence*. In that concurrence, Judge Rader correctly stated that "[a patentee] could not acquire product patent rights under [a claim] by merely adding new process limitations to an old product." *Atlantic Concurrence*,

974 F.2d at 1302. Such a claim would merely be a process claim, not a product-by-process claim.[6]

Where Judge Rader went astray, however, is when he claimed that "any attempt to limit the Supreme Court's rule to cases involving old products fails." *Id.* at 1303. But as discussed *infra*, every case where the Court found that a patented claim was not infringed because the process was not used was either a process claim or involved an old product. There is not a single Supreme Court case that involved a product-by-process claim on a new product. Moreover, Judge Rader's statement ignores over 110 years of precedent. In 1891, the Patent Office explicitly explained that when "an article of manufacture is a *new thing*, . . . and that article cannot be properly defined and discriminated from prior art otherwise than by reference to the process of producing it, a case is presented which constitutes an exception to the rule" that "an article of manufacture should not be defined by the process of producing [it]." *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891) (emphasis added).

In addition, Judge Rader's claim that whether a product is new or old is irrelevant ignores this Court's guidance. Judge Rader did not mention *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141 (1989), the *only* case from the Court that uses the term "product-by-process." The Court stated that

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[6] A process claim may be granted on a process for making an existing product as long as "the product as claimed can be made by another materially different process." *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009) (internal quotation omitted).

"[a]s long as the end product of the process is adequately defined and *novel* and nonobvious, a patent in the process may support a patent in the *resulting product*." *Id.* at 159 n.* (emphasis added). Thus, this Court's precedent clearly demonstrates that Judge Rader was wrong when he claimed that whether a product is new or old is irrelevant.

IV. The En Banc Majority Erred in Its Analysis of the Precedent of This Court and Other Courts

Although Judge Rader ignored the most relevant binding precedent from this Court, he claimed that other opinions of this Court compel the holding of the majority. In particular he pointed to *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1877); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222 (1880); *Merrill v. Yeomans*, 94 U.S. 568 (1877); *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884) ("BASF"); *The Wood-Paper Patent*, 90 U.S. 566 (1874); *Plummer v. Sargent*, 120 U.S. 442 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938). Although Judge Rader claimed that in each of "these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations," App. at 19, he only provided analysis regarding the *BASF* case. *Id.* at 21.

But Judge Rader's analysis is flawed because *BASF* did *not* involve a product-by-process claim. Judge Rader stated that the product at issue in that case was "artificial alizarine," *id.*, and that "artificial alizarines were known in the prior art." *Id.* at 20.

Thus, the product at issue in *BASF* was not a new product; therefore, the only possible patentable invention would be a new process for making that product.[7] But a "process" patent is not a "product-by-process" patent. In addition, the process claim at issue was found not infringed because "it does not satisfactorily appear that the process . . . will produce the defendants' article to any useful extent, if at all." *BASF*, 111 U.S. at 306. Therefore, *BASF* provides no guidance on the correct interpretation of "product-by-process" claims.[8]

Two other cases that the majority mentioned in passing as supporting its holding are the *Goodyear* cases: *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486 (1877), and *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222 (1880). But as the dissent explains, neither case supports the majority because they were not product-by-process claims, but rather process claims. App. 70.

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[7] Indeed, that was the holding in *BASF*. The product at issue "was an old article. While a new process for producing it was patentable, the product itself could not be patented." *BASF*, 111 U.S. at 311.

[8] Interestingly, BASF was involved in a true product-by-process case the same year that the Court decided *BASF*. *Pickhardt v. Packard*, 22 F. 530 (C.C.S.D.N.Y. 1884). The claim in *Pickhardt* was: "As a new manufacture, the coloring matter . . . obtained from [a process] . . .or by any other method which will produce a like result." *Id.* at 531. The *Pickhardt* court properly found that the defendant infringed that claim because even though there was no evidence regarding the process used by the defendant, any process that "produce[d] like results" to the patented product infringed the claim. *Id.* at 531.

Although the majority's analysis of the *Goodyear* cases is wrong, it is not unprecedented. Apparently, one of the defendants in *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258 (6th Cir. 1919), made the exact same argument. In *Dunn*, the circuit court used the same reasoning as the *Scripps* court, albeit 62 years earlier, and held that a product-by-process claim is infringed based only on the product being identical, even if the process used is different. That court held that it was irrelevant that "[t]he defendants' product is the result of a two-step wire-cutting process[, even though] plaintiff's patent describes a one-step process for making his product." *Id.* at 263. Moreover, that court explicitly rejected the majority's argument here that the *Goodyear* cases stand for the proposition "that a patent for a product is to be confined to the result of the described process." *Id.* at 261 n.2. Instead that court correctly held (as the dissent explained here) that infringement was not found in the *Goodyear* cases because "*[n]othing* which was not made by the process of vulcanization could be the equivalent of the 'hard rubber or vulcanite' of the claim." *Id.* (emphasis added).

The majority also cited to *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364 (1938) as support for its holding. But that case is also irrelevant because, as Judge Newman explained, it "involved no product-by-process claims, but rather claims that recite the properties of the product." App. 75; *accord* Passler, 49 U. Miami L. Rev. at 248 ("the claim in *General Electric* was a product claim").

Moreover, that case actually demonstrates that the majority opinion is directly contrary to the Court's precedent because the Court explicitly stated that "a claim may validly describe a new product with some reference to the method of production." *General Electric,* 304 U.S. at 373. In support of that statement it approvingly cited to two circuit cases, *Dunn* (discussed *supra*) and *Trussell Mfg. Co. v. Wilson-Jones Co.*, 50 F.2d 1027 (2d Cir. 1931), which both had held that product-by-process claims cover the product, and not the process.

In *Trussell*, the defendant argued that the claims were invalid due to "the claims [ ] being of a hybrid character, neither for a product nor for a process, but an attempt to define the article by the method of its manufacture." *Id.* at 1029. That court rejected the defendant's argument because while "an old article cannot be patented by claiming it as the product of a new process . . . if the article is new, it may be patented, and the claim will not be invalidated merely because it describes the article with some reference to the method of producing it." *Id.*

As stated *supra,* the majority opinion included a "laundry-list" of other Supreme Court cases, albeit with no analysis of why those cases are relevant.[9] App. 18-19. The majority did not, however, mention the *only* case from the Court that uses the term

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[9] Judge Newman, in her dissent, ably explains why none of these other Supreme Court cases support the majority's decision, *see* App. 68-77; therefore, Astellas will not repeat her analysis here.

"product-by-process." *Bonito*, 489 U.S. at 159 n.*. In *Bonito*, the Court analogized the Florida statute at issue in that case to a "product-by-process patent." *Id.* It noted that a product-by-process "claim 'is one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Id.* (quoting Donald S. Chisum, *Chisum on Patents* §8.05, 8-67 (1988). The Court then stated that "[a]s long as the end product of the process is adequately defined and novel and nonobvious, a patent in the process may support a patent in the resulting product." *Id.* Thus, when there is "a patent in the resulting product," one who makes such a product (regardless of the process used for making that product), would infringe that product claim. Thus, the majority's opinion cannot be squared with this Court's only direct statement on product-by-process claims.

In addition to Supreme Court cases, the majority also included a few cases from the Court of Customs and Patent Appeals and circuit court cases. Once again, the dissent ably explains why these other cases do not support the majority's opinion, and Astellas will not repeat that analysis here. *See* App. 50-57, 77-80. But Astellas will briefly discuss *In re Bridgeford,* 357 F.2d 679, 683 n.5 (C.C.P.A. 1966). Although cited by the majority, *Bridgeford* directly contradicts the majority's opinion. That court explained that for a product-by-process claim "the invention so defined is a product and not a process." *Id.* at 682. In so holding, that court overruled the suggestion in *In re Freeman,* 166 F.2d 178, 181 (C.C.P.A. 1948), that product-by-process

claims are actually process claims. *Bridgeford,* 357 F.2d at 683 n.6.

Apparently because it did not agree with the holding of *Bridgeford*, the majority found it necessary to belittle the Court of Customs and Patent Appeals by claiming that it was "a court with virtually no jurisdiction to address infringement litigation."[10] App. 23. That statement is incorrect because the C.C.P.A. regularly heard appeals of infringement cases coming from the International Trade Commission and its predecessor tribunals. *See, e.g., In re The Orion Co.,* 71 F.2d 458, 460-65 (C.C.P.A. 1934) (affirming the Tariff Commission's decision to embargo certain products for infringing a U.S. patent); *In re Von Clemm*, 229 F.2d 441, 445 (C.C.P.A. 1955) (affirming "the findings and recommendation of the Tariff Commission" after performing a detailed infringement analysis); *Coleco Indus., Inc. v. Int'l Trade Comm'n*, 573 F.2d 1247, 1257-58 (C.C.P.A. 1978) (affirming the decision of the ITC after performing a detailed infringement analysis); *Astra-Sjuco, A.B. v. Int'l Trade Comm'n*, 629 F.2d 682, 686-88 (C.C.P.A. 1980) (same); *Sealed Air Corp. v. Int'l Trade Comm'n*, 645 F.2d 976, 983-85 (C.C.P.A. 1981) (same).

The majority then claimed to find "ambivalence" in *Bridgeford's* holding because that court stated that "'some courts have construed such

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[10] It is ironic that the majority belittled the Court of Customs and Patent Appeals because the Federal Circuit voluntarily chose to make that court's precedent binding on the Federal Circuit. *South Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc).

claims as covering only a product made by the particular process set forth in the claim and not to the product per se.'" App. 24 (quoting *Bridgeford,* 357 F.2d at 683 n.5). The majority then made the incorrect claim that the term "'some courts'. . . as this court notes en banc, includes the United States Supreme Court and *every circuit* court to consider the question." App. 24 (emphasis added). Not only has the United States Supreme Court not addressed this question but, as shown by *Dunn* and *Trussell*, at least the second and sixth circuits did *not* "construe such claims as covering only a product made by the particular process set forth in the claim." *See Dunn*, 259 F. at 265; *Trussell*, 50 F.2d at 1029.

The majority also quotes *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) for the proposition that "product-by-process claims are limited by and defined by the process." App. 20. But again, although the language used was not as precise at it might have been, *Thorpe* was addressing an old product made by an allegedly new process and its holding was that "[i]f the *product* in the product-by-process claim *is the same* as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *Id.* at 697 (emphasis added). Indeed, this Court rejected the majority's interpretation of *Thorpe*, when it explained that, in *Thorpe*, the "product-by-process patent [was] properly denied where [the] *end result* was indistinguishable from prior art." *Bonito*, 489 U.S. at 159 n.* (emphasis added). Thus, whether the process in the product-by-process claim was a claim limitation was never at issue in *Thorpe.*

As shown above, the case law that the majority cited not only does not support the majority, but instead, it actually supports the dissent. Moreover, this case is much more than the typical disagreements that occur in contested opinions, where the majority describes cases one way, the dissent describes cases the other way, and the petitioner agrees with the dissent. While that is certainly true here, there is an additional factor.

The arguments made by Judge Rader in his majority opinion are virtually identical to the arguments he made in both his *Atlantic* and *Atlantic Concurrence* opinions. *See* App. 17-20 (citing *Atlantic* for its "discussi[on] of each of the [Supreme Court] cases" listed in the en banc opinion and stating that it would "adopt[ ] the rule in *Atlantic*"). Similarly, the arguments that Judge Newman made in her dissent are virtually identical to the arguments in her opinion in *Scripps* and in her dissent from the denial of granting rehearing en banc in *Atlantic*. *Compare* App. 50-60, 66-80 (explaining that the majority's holding is not supported by the Supreme Court cases, the circuit court cases and the C.C.P.A. cases that the majority cites and further explaining that *Bridgeford* and *Thorpe* demonstrate that product-by-process claims cover the product) *with Scripps*, 927 F.2d at 1583 (explaining that *Bridgeford* and *Thorpe* demonstrate that product-by-process claims cover the product) *and Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1279, 1285-93 (Fed. Cir. 1992) (Newman, J., dissenting) (explaining that *Atlantic's* holding is not supported by the Supreme Court cases, the circuit

court cases and the C.C.P.A. cases that *Atlantic* cites and further explaining that *Bridgeford* and *Thorpe* demonstrate that product-by-process claims cover the product).

In the seventeen years since the *Atlantic* opinions, dozens of law review articles have been written about product-by-process claims and the different interpretations of those claims by Judge Rader and Judge Newman. As one commentator explained:

> The *Atlantic* opinion is *problematic* in several respects. First, the *Atlantic* panel took language from Supreme Court and C.C.P.A. opinions *out of context*. . . . [In addition o]ften, the courts have made broad assertions in dicta that are not entirely accurate. The *Atlantic* decision relies heavily on this dicta in concluding that product-by-process claims are limited by the process described therein in all cases. The dicta relied on by the *Atlantic* panel, however, primarily involved claims in which a new process was applied to an old or obvious product. Most of the Supreme Court cases on this issue involved old products which could only be distinguished from the prior art by the method used to create the product. In these situations, the invention is the process, not the product.

Michael J. Schutte, *Patent Law: Controversy in the Federal Circuit Over Product-By-Process Claims – Atlantic Thermoplastics Co. v. Faytex Corp. . . .*, 19 Dayton L. Rev. 283, 307-8 (Fall, 1993) (emphasis added).

Indeed, the majority of commentators agree with Mr. Schutte and find that Judge Newman's analysis is much more accurate, especially when it comes to reviewing the Supreme Court precedent, than is Judge Rader's analysis.[11] Thus, this is not merely a case of "he said/she said" (with the petitioner joining in with "she said"), but rather numerous independent third parties have already

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[11] *See, e.g.*, Passler, 49 U. Miami L. Rev. at 248 ("The Atlantic Thermoplastics analysis of Supreme Court precedent was erroneous."); Brian S. Tomko, Comment, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-By-Process Patents*, 60 Brooklyn L. Rev., 1693, 1726 (Winter, 1995) ("The Supreme Court precedent gathered by Judge Rader does not support the proposition that the Court intended to limit a product-by-process claim's scope to the process and the product made by that process."); Alan I. Cohen, Note, *A Prescription for the Treatment of Product-By-Process Patent Infringement*, 67 St. John's L. Rev. 923, 932 (Fall, 1993) ("the majority in *Atlantic Thermoplastics* failed to differentiate between product-by-process claims in which the product could be defined by its structure or characteristics and those in which it could not"); William E. McGowan, Comment, *Patent Law – Limiting Infringement Protection for Product-by-Process Claims – Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992), 27 Suffolk U. L. Rev. 300, 307 (Spring, 1993) ("By failing to make a distinction between [cases discussing old and new products], the *Atlantic* court may have erroneously narrowed the scope of infringement protection of product-by-process claims for novel and non-obvious products.").

weighed in that the majority opinion here is wrong as a matter of law because that opinion is virtually identical to the opinion in *Atlantic*. Consequently, the Court should grant the petition for *certiorari* to decide whether the en banc opinion conflicts with the Court's precedent.

V. The En Banc Decision Necessitated that the Panel Improperly Rewrite the Claims

As both of the dissenting opinions noted, the error in the majority's opinion is further demonstrated by its treatment of the phrase "obtainable by."[12] The two independent claims at issue in this petition are claims 2 and 5, which state:

> 2. Crystalline [cefdinir] which is *obtainable by* acidifying a solution containing [cefdinir] at room temperature or under warming.
>
> 5. Crystalline [cefdinir] which is *obtainable by* dissolving [cefdinir] in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room

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[12] This section of the opinion is not part of the en banc section, but it directly flows from the en banc's ruling, which is why both of the dissents discussed this issue. *See* App. 83-84 (Newman, J., dissenting); App. 88 (Lourie, J., dissenting).

> temperature and allowing the solution to stand.

App. 7 (emphasis added).

The majority opinion simply ignored that the patent claimed cefdinir "which is *obtainable* [by a process]," and instead improperly redefined the claim to cover cefdinir "which is *obtained* [by a process]." *See* App. 29. Here, the "plain import" of the claims could not be more clear. The starting point for claim construction is the words of the claim. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). "Obtainable" has a well-known plain meaning. It is defined, according to Webster's, as "capable of being obtained." Webster's Third New International Dictionary at 1559 (1993). It does not mean "obtained by." The majority, however, contended that it was proper to rewrite "obtainable by" to "obtained by," because otherwise claims 2 through 5 would be duplicative of each other. *See* App. 28. But the majority is incorrect for two reasons. First, "[c]ourts cannot rewrite claim language." *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008). Second, inventors have the right to define their invention how they choose. As the majority noted, it can be difficult to prove infringement for product-by-process claims. Therefore, Astellas chose to claim multiple processes because if a defendant's product was made by any of the claimed processes, there would be few, if any, evidentiary issues regarding infringement. If, on the other hand, the defendant's product was made by a different process, Astellas could still prove infringement if it could show that

the product was the same as the product described in its product-by-process claims. In any event, even if the panel was right that claims 2 and 5 are duplicative of each other, the clear language of the claims "trumps the doctrine of claim differentiation." *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1582 (Fed. Cir. 1997).

Moreover, the Federal Circuit's unilateral decision to decide that "obtainable by" actually means "obtained by" puts thousands of current patents at risk. Indeed, in the last twenty years, Petitioner's research demonstrates that over 11,000 patents have claims that include the phrase "obtainable by."[13] The Court should grant the petition to decide whether it was proper for the Federal Circuit to emasculate product-by-process claims.

VI. Product-by-Process Patents Promote the Progress of Science

The majority opinion claimed that, due to increasingly sophisticated technology, product-by-process claims may no longer be necessary because few structures will be "too complex to analyze." App. 25. That statement is incorrect. Indeed, product-by-

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[13] A search in the Lexis "Utility, Design and Plant Patents" database using the search term "obtainable by" in the segment "claims" for patents issued between August 26, 1989, and August 26, 2009, identified over 11,000 patents with claims including the term "obtainable by." As patent terms are generally twenty years from the date of filing, the vast majority of those patents are still in effect.

process claims are more important now than they have ever been because the "protection provided by product-by-process patents is particularly necessary in the areas of pharmaceuticals and biotechnology, due to the high costs of research and investment." Cohen, 67 St. John's L. Rev. at 936.

Many of the latest chemical claims and biotechnology claims such as "recombinant DNA and molecular purification" can only be patented "by reference to the process used to manufacture [them]--i.e., by using [ ] product-by-process claim[s]." Tomko, 60 Brooklyn L. Rev. at 1698; *see also* Kevin J. McGough and Daniel P. Burke, *A Case for Expansive Patent Protection of Biotechnology Inventions*, 6 Harv. J. Law & Tec. 85, 101 (Fall, 1992) ("Since further innovation will require great expense and laborious research, investors need reasonable assurances that expansive product or product-by-process patent protection will facilitate attractive returns on investment. This is particularly true regarding . . . DNA sequence claims and claims to host cells."). Biotechnology companies may be particularly affected by the majority's holding:

> Given the exorbitant expense incurred in researching and developing new products, the biotechnology industry depends upon patent protection for newly developed pharmaceuticals. Because some products of biotechnology are incapable of independent structural definitions, patentees often opt to claim these products using product-by-process

> language. In *Atlantic* [and by extension the majority's holding here], the Federal Circuit impairs the biotechnology industry's ability to obtain patent protection by narrowly construing the scope of infringement protection of product-by-process claims as applying only to the specific manufacturing process of the drug.

McGowan, 27 Suffolk U. L. Rev. at 308.

Moreover, product-by-process claims have become so important that the FDA now allows product-by-process claims to be listed in the Orange Book for new drugs.[14] Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 Duke L. & Tech. Rev. 18 (Aug. 2003) ("Product-by-process patents are listable in the Orange Book; . . . [provided] that the patent being submitted is a product-by-process patent in which the product claimed is novel, as opposed to the process being novel . . . [because] process patents . . . cannot be submitted for listing"); *see* 21 C.F.R. § 314.53(c)(2)(i)(L) (a product-by-process patent may be listed if "the product claimed is novel").

But the Federal Circuit's decision here contradicts the FDA's decision. The FDA allowed

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[14] The "Orange Book" is the colloquial name given to the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations." Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, Mich. St. L. Rev. 631, 634 (Fall, 2007).

product-by-process claims explicitly because they are claims for products, not processes, as process patents can not be included in the Orange Book. *Id.* Thus, if the Court does not review the decision here, numerous product-by-process patent claims may lose their protection of being listed in the Orange Book.

Finally, Judge Rader's contention that inventors may still "stake claims in product-by-process terms," App. 23, will bring cold comfort to pharmaceutical or biological researchers who have uncovered a new important product, but are not able to accurately describe the structure of that important product. Because the only part of the claim the Federal Circuit will protect is the process, the researchers would most likely file a process claim, rather than what one commentator called "a glorified process patent."[15] *See* Tomko, 60 Brooklyn L. Rev. at 1696 ("the *Atlantic* panel pared the scope of a product-by-process patent to that of a glorified process patent"). Thus, the researchers may lose the fruits of their valuable research when "a competing biotechnology company [ ] pirate[s the] pharmaceutical product patented by a product-by-process claim by slightly altering the method of manufacturing the drug." McGowan, 27 Suffolk U. L. Rev. at 308.

The United States Constitution, Art. I, Sec. 8, Clause 8 maintains that patents "promote the

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[15] Indeed, in some respects, product-by-process claims are less than "glorified process patents" because not only must the patentee prove that the alleged infringer practices the process claimed, but then must also prove that the resulting product is, in fact, the product claimed.

progress of science . . . by securing for limited times to . . . inventors the exclusive right to their . . . discoveries." (Initial Capitalization omitted). "Product-by-process claims fill an important gap in patent law by furnishing an inventor who cannot describe her invention in terms precise enough to gain a conventional product patent with the means to gain the same protection." Tomko, 60 Brooklyn L. Rev. at 1738. Thus, product-by-process patents that provide strong protection for the product described are an important part of "promot[ing] the progress of science." As such, the Court should grant the petition for *certiorari* to decide whether the Federal Circuit's weakening to the point of destroying product-by-process claims complies with the Court's precedent and is in the nation's interest.

CONCLUSION

For the foregoing reasons, the petition for *certiorari* should be granted.

Respectfully submitted,

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APPENDIX

ABBOTT LABORATORIES, Plaintiff-Appellant, and ASTELLAS PHARMA, INC., Plaintiff-Appellant,

v.

SANDOZ, INC., Defendant-Appellee, and SANDOZ GMBH, Defendant, and TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants-Appellees, and RANBAXY LABORATORIES, LTD. and RANBAXY, INC., Defendants, and PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, Defendants. LUPIN LIMITED, Plaintiff/Counterclaim Defendant-Appellee, and LUPIN PHARMACEUTICALS, INC., Counterclaim Defendant-Appellee, v. ABBOTT LABORATORIES, Defendant/Counterclaimant-Appellant, and ASTELLAS PHARMA, INC., Defendant/Counterclaimant-Appellant.

2007-1400, 2007-1446

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

566 F.3d 1282

May 18, 2009, Decided

DISPOSITION: AFFIRMED.

COUNSEL: James F. Hurst, Winston & Strawn LLP, of Chicago, Illinois, argued for all plaintiffs-appellants in 2007-1400 and defendants/counterclaimants-appellants in 2007-1446. With him on the briefs for Abbott Laboratories were Todd J. Ehlman, Kathleen B. Barry, and Ivan M. Poullaos, and Steffen N. Johnson, of Washington, DC. Of counsel on the brief for Abbott Laboratories were William F. Cavanaugh, Jr., Jeffrey I.D. Lewis, and Stuart E. Pollack, Patterson Belknap Webb & Tyler LLP, of New York, New York. Of counsel was John C. Knapp. On the briefs for Astellas Pharma, Inc., were Richard D. Kelly, Stephen G. Baxter and Frank J. West, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., of Alexandria, Virginia.

Meredith Martin Addy, Brinks, Hofer, Gilson & Lione, of Chicago, Illinois, argued for defendant-appellee Sandoz, Inc. With her on the brief were Thomas J. Filarski, Mark H. Remus, C. Noel Kaman, and Laura A. Lydigsen. Of counsel was Rashad L. Morgan.

Thomas J. Meloro, Jr., Wilkie Farr & Gallagher LLP, of New York, New York, argued for defendants-appellees Teva Pharmaceuticals USA, Inc., et al. With him on the brief was Neal K. Feivelson. Of counsel were Michael W. Johnson and Alexander H. Swirnoff.

Deanne M. Mazzochi, Rakoczy Molino Mazzochi Siwik, LLP, of Chicago, Illinois, argued for plaintiff/counterclaim defendant-appellee Lupin Limited

and counterclaim defendant-appellee, Lupin Pharmaceuticals, Inc. in 2007-1446. With her on the brief were William A. Rakoczy, Paul J. Molino, and Amy D. Brody.

JUDGES: Before RADER, PLAGER, and BRYSON, Circuit Judges. MICHEL, Chief Judge, and RADER, BRYSON, GAJARSA, LINN, DYK, PROST, and MOORE, Circuit Judges, have joined Section III.A.2 of the opinion. Dissenting opinion as to Section III.A.2 filed by NEWMAN, Circuit Judge, in which MAYER and LOURIE, Circuit Judges, join. Dissenting opinion filed by LOURIE, Circuit Judge. SCHALL, Circuit Judge, did not participate as a member of the en banc court.

OPINION BY: RADER

OPINION

RADER, *Circuit Judge.*

In this case, the same patent, U.S. Patent No. 4,935,507 (the '507 patent), occasions litigation in both the United States District Court for the Eastern District of Virginia and the United States District Court for the Northern District of Illinois. The Virginia District Court granted the motion of Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively Lupin) for summary judgment of noninfringement. In the other case, the Illinois District Court denied a preliminary injunction to Abbott Laboratories, the exclusive licensee of the '507 patent, based on the claim construction from the Eastern District of Virginia.

Because the Eastern District of Virginia correctly construed the claims of the '507 patent and correctly discerned no genuine issues of material fact on literal infringement of claims 2-5 or infringement by equivalents of claims 1-5, this court affirms its partial summary judgment of noninfringement. Likewise, this court affirms the Northern District of Illinois' denial of Abbott's motion for a preliminary injunction, based in large part on the same correct claim construction.

I.

Abbott Laboratories, the exclusive licensee of the '507 patent, markets crystalline cefdinir according to the '507 patent under the trade name Omnicef. The Virginia case arose when Lupin sought a declaratory judgment of noninfringement against Abbott Laboratories and Astellas Pharma Inc., the owner of the '507 patent (collectively Abbott). The Food and Drug Administration had previously approved Lupin's Abbreviated New Drug Application (ANDA) to market a generic version of Omnicef. Lupin's generic product contains almost exclusively the Crystal B form of crystalline cefdinir (cefdinir monohydrate), whereas Abbott's Omnicef product contains the Crystal A form of crystalline cefdinir (cefdinir anhydrate). Further, Lupin makes its products with processes other than those claimed in the '507 patent. For these reasons, Lupin brought the Virginia action to clarify that its proposed product would not infringe a valid patent. Abbott counterclaimed for infringement. The Eastern District of Virginia construed the claims, *Lupin Ltd. v. Abbott Laboratories*, 484 F. Supp. 2d 448 (E.D. Va. 2007) (*Lupin CC Order*), and

ultimately granted-in-part Lupin's motion for summary judgment of noninfringement, as to both literal and equivalent infringement for claims 2-5 and as to equivalent infringement for claim 1, *Lupin Ltd. v. Abbott Labs.*, 491 F. Supp. 2d 563 (E.D. Va. 2007) (*Lupin SJ Order*). The parties stipulated to the dismissal without prejudice of the remaining claims (invalidity) and counterclaims (literal infringement of claim 1).

In the Illinois action, Abbott sued Sandoz, Inc. and Sandoz GmbH (collectively Sandoz), Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. (collectively Teva), Ranbaxy Laboratories, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical (all defendants, collectively, Sandoz and Teva) for infringement of the '507 patent. Like Lupin, Sandoz and Teva had previously filed ANDAs, seeking to market generic versions of Omnicef. Abbott sought a preliminary injunction in the Illinois case. For purposes of that motion, the parties agreed to adopt the Eastern District of Virginia's claim construction from the *Lupin* case. *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767 (N.D. Ill. 2007) (*Sandoz PI Order*). Despite this agreement, the parties to the *Sandoz* case disagreed as to how to interpret some of the Eastern District of Virginia's constructions, necessitating some clarification by the Northern District of Illinois. 486 F. Supp. 2d at 770-71 (disputing "Crystal A," "peaks," and "about," and seeking construction of "powder X-ray diffraction pattern," which the Eastern District of Virginia had not defined). Ultimately, the Northern District of Illinois, based on the claim

construction from Virginia, denied the preliminary injunction.

Both cases arrived at this court on appeal. This court heard the cases together and decides them together with this decision.

II.

The '507 patent has five claims, all of which Abbott asserts against Lupin as well as Sandoz and Teva. Claim 1 claims crystalline cefdinir, using its chemical name, and defining its unique characteristics with powder X-ray diffraction (PXRD) angle peaks:

> 1. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem.-4-carboxylic acid (syn isomer) which shows the peaks at the diffraction angles shown in the following table in its powder X-ray diffraction pattern:
>
> | diffraction angle [degree] |
> | --- |
> | about 14.7 [degrees] |
> | about 17.8 [degrees] |
> | about 21.5 [degrees] |
> | about 22.0 [degrees] |
> | about 23.4 [degrees] |
> | about 24.5 [degrees] |
> | about 28.1 [degrees] |

'507 patent, col.16 ll.13-27. In contrast, claims 2-5 claim crystalline cefdinir, without any PXRD peak limitations, but with descriptions of processes used to obtain the crystalline cefdinir. Claims 2 and 5 are independent:

> 2. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by acidifying a solution containing 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) at room temperature or under warming.
>
> 5. Crystalline 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) which is obtainable by dissolving 7-[2-(2-aminothiazol-4-yl)-2-hydroxyiminoacetamido]-3-vinyl-3-cephem-4-carboxylic acid (syn isomer) in an alcohol, continuing to stir the solution slowly under warming, then cooling the solution to room temperature and allowing the solution to stand.

Id. at col.16 ll.29-34, 43-50.

These claims use PXRD as a way to claim the structure and characteristics of the unique crystalline form. PXRD is a method for identifying and distinguishing different crystalline compounds. The method beams X-rays toward a powdered chemical. The method then measures the ways the rays reflect or bend upon contact with the chemical. The diffrac-

tion angles and intensities vary with the type and purity of the test compound. A graph then plots the diffraction angle on one axis and the intensity on another. These graphs yield a unique "fingerprint" for each crystalline form of a chemical. A more sensitive form of X-ray diffraction is single crystal X-ray diffraction (SCXRD). As this name suggests, this method uses only a single crystal as a sample. SCXRD does not detect intensity, but produces a more precise diffraction angle measurement.

The '507 patent was not the first cefdinir patent. Rather, Astellas' prior art U.S. Patent No. 4,559,334 (the '334 patent) describes the discovery of cefdinir as a compound demonstrating high antimicrobial activity. *'334 patent*, col.11 ll.18-24. The *'334 patent* expired on May 6, 2007.

The '507 patent claims priority to Japanese Patent Application No. 62-206199 (the JP '199 application), which claimed two crystalline forms of cefdinir, "Crystal A" and "Crystal B." The JP '199 application claimed Crystals A and B very specifically, defining Crystal A by three infrared (IR)-absorption wavelengths and sixteen PXRD angles and intensities. In contrast, Crystal B featured five IR-absorption wavelengths and twenty-one PXRD angles/intensities.

Despite using the JP '199 application for priority, the '507 patent's specification differs significantly. Specifically, Abbott (actually Fujisawa Pharmaceutical Co., Ltd., Astellas' predecessor in interest) jettisoned the Crystal B disclosure found in the JP '199 application and crafted broader claims in its prosecution of the '507 patent. Because the JP '199 appli-

cations defines Crystal A and Crystal B physiochemically rather than structurally, the forms actually represent subgenuses of crystalline cefdinir. Thus Crystals A and B comprise crystalline forms of varying structures, which in the context of this case means varying levels of hydration.

The Eastern District of Virginia construed the claim terms "crystalline," "shows," "peaks," and "about" as follows:

> 1) "crystalline" means "Crystal A as outlined in the specification";
>
> 2) "shows" requires the display of a powder X-ray diffraction pattern which demonstrates the existence of the relevant peaks to a scientifically acceptable degree of certainty either visually or by other appropriate means of data display;
>
> 3) "peaks" is the plural of "peak;" a "peak exists at a powder X-ray diffraction angle that corresponds to an intensity measurement greater than measurements attributable to "noise" if that angle is immediately preceded by and followed by powder X-ray diffraction angle with a lower intensity measurement; "noise" refers to those portions of a PXRD pattern produced by intrinsic measurement error, and which cannot be associated with a scientifically significant quantity of the material which is the subject of the PXRD test;

> 4) "about" encompasses measurement errors inherently associated with powder X-ray diffraction testing.

Lupin CC Order, 484 F. Supp. 2d at 459, 466. The Eastern District of Virginia also concluded that claims 2-5 were product-by-process claims. *Id.* Later the district court concluded that the process terms of claims 2-5, indicated by the phrase "obtainable by," limit the claims to the specified processes and process steps. In reaching that conclusion, the trial court followed this court's opinion in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). *Lupin SJ Order*, 491 F. Supp. 2d at 567-68; *Lupin Ltd. v. Abbott Labs.*, No. 3:06-CV-400 (E.D. Va. May 10, 2007) (*Lupin PbyP Order*). In the *Lupin* appeal, Abbott challenges only the Eastern District of Virginia's constructions of "crystalline" and "obtainable by."

III.

Evaluation of a summary judgment of noninfringement requires two steps: claim construction, which this court reviews without deference, *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1451 (Fed. Cir. 1998) (en banc), and comparison of the properly construed claims to the accused product, process, or composition of matter, which in the context of summary judgment also occurs without deference, *see Ormco Corp. v. Align Technologies, Inc.*, 498 F.3d 1307, 1312 (Fed. Cir. 2007). Although infringement by equivalency is a question of fact, this court may affirm summary judgment "where no reasonable fact finder could find equivalence." *Sage*

Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed. Cir. 1997) (citing *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 39 n.8, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997).

A. Claim Construction

Because the claims define the patent right, *see Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004), naturally "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). But the claims "must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995)* (en banc), *aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996).* A patent's specification provides necessary context for understanding the claims, and "is always highly relevant to the claim construction analysis." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). While equally true in a general sense, sometimes the specification offers practically incontrovertible directions about claim meaning. For example, inventors may act as their own lexicographers and give a specialized definition of claim terms. *See id.* at 1316. Likewise, inventors and applicants may intentionally disclaim, or disavow, subject matter that would otherwise fall within the scope of the claim. *See id.*

When consulting the specification to clarify the meaning of claim terms, courts must take care not to import limitations into the claims from the specifica-

tion. This court has recognized the "fine line between" the encouraged and the prohibited use of the specification. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). When the specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application "unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)). By the same token, the claims cannot "enlarge what is patented beyond what the inventor has described as the invention." *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1140 (Fed. Cir. 2003) (quoting *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001)). Thus this court may reach a narrower construction, limited to the embodiment(s) disclosed in the specification, when the claims themselves, the specification, or the prosecution history clearly indicate that the invention encompasses no more than that confined structure or method. *See Liebel-Flarsheim*, 358 F.3d at 908.

Along with the specification, the prosecution history is "intrinsic evidence" of the meaning of the claims, because it "provides evidence of how the [United States Patent & Trademark Office (PTO)] and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. Although often producing ambiguities occasioned by ongoing negotiations between the inventor and the PTO, "the prosecution history can often inform the meaning of the claim language

by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* "[C]lear and unmistakable" statements during prosecution may also disavow claim scope. *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008) (quoting *Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 1136 (Fed. Cir. 2006)).* Again owing in part to the inherent ambiguities of prosecution history, the doctrine of prosecution disclaimer only applies to unambiguous disavowals. *See id.* at 1375.

1. "crystalline"

The Eastern District of Virginia's construction of "crystalline" in claims 1-5 as "Crystal A" included the important caveat "as outlined in the specification." *Lupin CC Order*, 484 F. Supp. 2d at 459. Although the Eastern District noted the parties agreed that "crystalline" ordinarily means exhibiting "uniformly arranged molecules or atoms," *id.* at 454, the court relied on the language of the claims themselves, the specification, and the prosecution history to arrive at the more specific meaning recited in the specification.

The '507 specification states that "Crystal A of the compound (I) [cefdinir] shows its distinguishing peaks" at the seven particular PXRD angles enumerated in claim 1. 507 *patent* col.1 ll.51-62. Indeed, the phrase "Crystal A of the compound (I)" appears throughout the written description, and the patent offers the following definition: "any crystal of the compound (I) which shows substantially the

same diffraction pattern [as in the table in col.1/claim 1] is identified as Crystal A of the compound (I)." *Id.* at col.1 l.67-col.2 l.2. As the Eastern District correctly concluded:

> Had Astellas intended, in the chart found in column 1, to distinguish Crystal A from other forms of crystalline cefdinir that also fall within the scope of claim 1, it would have listed, at a minimum, an eighth peak associated only with Crystal A. However, by listing in column 1 only the same seven 'distinguishing' peaks featured in Claim 1, Astellas confirmed that Crystal A was synonymous with the invention listed in Claim 1.

Lupin CC Order, 484 F. Supp. 2d at 456-57. The problem, within the confines of claim 1, is that defining "crystalline" as "Crystal A," where "Crystal A" incorporates the seven PXRD peak limitations, arguably renders the remainder of that claim redundant. To distinguish the invention, however, the specification refers several times to "Crystal A of the compound (I) of the present invention," *see, e.g.*, '507 patent, col.2 ll.15-17, and offers no suggestion that the recited processes could produce non-Crystal A compounds, even though other types of cefdinir crystals, namely Crystal B, were known in the art. As noted earlier, the Crystal B formulation actually appears in the parent JP '199 application. Thus, Abbott knew exactly how to describe and claim Crystal B compounds. Knowing of Crystal B, however, Abbott chose to claim only the A form in the '507 patent. Thus, the trial court properly limited the term

"crystalline" to "Crystal A." The trial court's definition correctly identifies claim 1's literal scope.

Unlike claim 1, claims 2-5 do not recite the seven PXRD peaks expressly associated with Crystal A in the '507 specification. Nonetheless, the Eastern District of Virginia limited "crystalline" to "Crystal A" in these claims as well, The trial court gave two reasons for this limitation. First, "[t]he process steps detailed in those claims [claims 2-5] correspond with the processes for making Crystal A disclosed in the specification under the heading 'The Process For Preparing Crystal A of The Compound (I).'" *Id.* at 457 (quoting '507 patent, col.2 ll.13-14). Second, the parent JP '199 application recited these steps "to distinguish between preparations of Crystal A and Crystal B." *Id.* (citing JP '199 application, col.6 ll.1-25).

In limiting "crystalline" to "Crystal A" in claims 1-5, the Eastern District of Virginia did not improperly import the preferred embodiment into the claims. Initially, Crystal A is the only embodiment described in the specification. As discussed above, the specification's recitation of Crystal A as its sole embodiment does not alone justify the trial court's limitation of claim scope to that single disclosed embodiment. *See Liebel-Flarsheim*, 358 F.3d at 906 ("[T]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). In this case, however, the rest of the intrinsic evidence, including the prosecution history and the priority JP '199 application, evince a clear intention to limit the '507 patent

to Crystal A as defined by the seven PXRD peaks in the specification and in claim 1.

Initially, the Eastern District of Virginia properly considered the JP '199 application as relevant objective evidence of the inventor's knowledge at the filing of the '507 patent. While statements made during prosecution of a foreign counterpart to a U.S. patent application have a narrow application to U.S. claim construction, *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006), in this case the JP '199 application is part of the prosecution history of the '507 patent itself. Indeed the *'507 patent* claims priority from the JP '199 application. Furthermore, the trial court did not rely on attorney argument or amendments during a foreign prosecution as in *Pfizer*, but consulted only the contents of the foreign priority application. The JP '199 application strongly suggests that the '507 patent intentionally excluded Crystal B compounds. As discussed above, the JP '199 application establishes unequivocally that Abbott knew and could describe both Crystal A and Crystal B. Abbott could have retained the disclosure of Crystal B to support the broader claims of the '507 patent, but instead disclosed and claimed A alone.

Furthermore, the prosecution history of the '507 patent shows a clear and intentional disavowal of claim scope beyond Crystal A. Co-inventor Takao Takaya, who prepared samples according to Examples 14 and 16 of the prior art '334 patent and a sample of "Crystal A of the present application," offered a declaration that Crystal A was more stable than the prior art samples from the '334 patent. An analytical chemist, Yoshihiko Okamato, corroborated

this evidence. J. A. 501-04. Beyond these declarations, the applicant specifically limited the invention to Crystal A: "the *method of preparation* of the crystalline form of the presently claimed compounds is not considered the heart of the present invention. The crystalline form of the compound represents the inventive concept hereof, and it is clear that [the '334 patent] does not anticipate or suggest said crystalline form." J. A. 511 (Response to Office Action of May 11, 1989, received October 27, 1989, at 6).

Given the exclusive focus on Crystal A in the specification as well as the prosecution history of the '507 patent, the Eastern District of Virginia properly limited "crystalline" in claims 1-5 to "Crystal A."

2. proper interpretation of product-by process claims[1]

This court addresses Part III.A.2 of this opinion en banc, which addresses the proper interpretation of product-by-process claims in determining infringement.

Claims 2-5 of the '507 patent begin by reciting a product, crystalline cefdinir, and then recite a series of steps by which this product is "obtainable." The Eastern District of Virginia correctly categorized claims 2-5 as product-by-process claims. On appeal,

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[1] This court, *sua sponte*, took en banc Section III.A.2 before issuing a panel opinion. The following judges join this section of the opinion: Chief Judge Michel and Judges Rader, Bryson, Gajarsa, Linn, Dyk, Prost, and Moore. Judges Newman and Lourie dissent in separate opinions. Judges Mayer and Lourie join in Judge Newman's dissent. Judge Schall did not participate as a member of the en banc court.

Abbott argues that the Eastern District erred in construing the process steps of claims 2-5 under the rule in *Atlantic Thermoplastics*, 970 F.2d at 846-47, that "process terms in product-by-process claims serve as limitations in determining infringement," rather than in accordance with *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("[T]he correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."). This court takes this opportunity to clarify en banc the scope of product-by-process claims by adopting the rule in *Atlantic Thermoplastics*.

In *Atlantic Thermoplastics*, this court considered the scope of product-by-process claim 26 in the patent at issue: "[t]he molded innersole produced by the method of claim 1." 970 F.2d at 836. The patentee urged that competing, indistinguishable innersoles made by a different method nonetheless infringed claim 26. *Id. at 838.* This court rejected the patentee's position. This court in *Atlantic Thermoplastics* construed product-by-process claims as limited by the process. Id. at 846-7.

This rule finds extensive support in Supreme Court opinions that have addressed the proper reading of product-by-process claims. *See Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493, 23 L. Ed. 952, 1877 Dec. Comm'r Pat. 171 (1877) ("The process detailed is thereby made as much a part of the invention as are the materials of which the product is composed."); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880) ("[T]o constitute infringement of the patent, both the material of which

the dental plate is made . . . and the process of constructing the plate . . . must be employed."); *Merrill v. Yeomans,* 94 U.S. 568, 24 L. Ed. 235, 1877 Dec. Comm'r Pat. 279 (1877); *Cochrane v. Badische Anilin & Soda Fabrik,* 111 U.S. 293, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884) (BASF); *The Wood-Paper Patent,* 90 U.S. 566, 596, 23 L. Ed. 31 (1874); *Plummer v. Sargent,* 120 U.S. 442, 7 S. Ct. 640, 30 L. Ed. 737 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.,* 304 U.S. 364, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 (1938); *see also Atl. Thermoplastics,* 970 F.2d at 839-42 (discussing each of these cases). In these cases, the Supreme Court consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations. In addition, the binding case law of this court's predecessor courts, the United States Court of Customs and Patent Appeals (*see In re Hughes,* 496 F.2d 1216, 1219 (CCPA 1974) (acknowledging that "true product claims" are "broader" in scope than product-by-process claims)), and the United States Court of Claims (*see Tri-Wall Containers v. United States,* 408 F.2d 748, 751, 187 Ct. Cl. 326 (Ct. Cl. 1969)), followed the same rule.

This court's sister circuits also followed the general rule that the defining process terms limit product-by-process claims. *See, e.g., Hide-Ite Leather v. Fiber Prods.,* 226 F. 34, 36 (1st Cir. 1915) ("It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process."); *Paeco,*

Inc. v. Applied Moldings, Inc., 562 F.2d 870, 876 (3d Cir. 1977) ("A patent granted on a product claim describing one process grants no monopoly as to identical products manufactured by a different process."). Indeed, this court itself had articulated that rule: "For this reason, even though *product-by-process claims are limited by and defined by the process*, determination of patentability is based on the product itself." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (emphasis added).

The Supreme Court has long emphasized the limiting requirement of process steps in product-by-process claims. In *BASF*, the Court considered a patent relating to artificial alizarine. Specifically, the patent claimed "[a]rtificial alizarine, produced from anthracine or its derivatives by either of the methods herein described, or by any other method which will produce a like result." 111 U.S. at 296 (quoting U.S. Patent Reissue No. RE 4,321). In turn, the specification generally described a method for making artificial alizarine involving anthracine or its derivatives. Alizarine had been in use for thousands of years as a red textile dye, traditionally extracted from madder root. Pure alizarine has the chemical formula C[14]H[8]O[4], but "artificial alizarines" available in the market at the time of the litigation varied from almost completely pure alizarine, to combinations of alizarine and anthrapurpurine, to pure purpurine containing no alizarine whatsoever. *Id.* at 309-10. The defendant's product contained approximately sixty percent anthrapurpurine. Thus both alizarine and artificial alizarines were known in the prior art. The Supreme Court clearly articulated some of the scope and validity problems that

arise when process limitations of product-by-process claims are ignored:

> [The defendant's product] is claimed by the plaintiff to be the artificial alizarine described in No. 4,321, and to be physically, chemically, and in coloring properties similar to that. But what that is is not defined in No. 4,321, except that it is the product of the process described in No. 4,321. Therefore, unless it is shown that the process of No. 4,321 was followed to produce the defendant's article, or unless it is shown that that article could not be produced by any other process, the defendant's article cannot be identified as the product of the process of No. 4,321. Nothing of the kind is shown.
>
> * * *
>
> If the words of the claim are to be construed to cover all artificial alizarine, whatever its ingredients, produced from anthracine or its derivatives by methods invented since Graebe and Liebermann invented the bromine process, we then have a patent for a product or composition of matter which gives no information as to how it is to be identified. *Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.*

Id. at 310 (emphasis added).

After *BASF*, the Supreme Court continued to emphasize the importance of process steps in evaluating the infringement of product-by-process claims. *See, e.g., Plummer*, 120 U.S. at 448 ("[W]hatever likeness that may appear between the product of the process described in the patent and the article made by the defendants, their identity is not established unless it is shown that they are made by the same process."); *Gen. Elec. Co.*, 304 U.S. at 373 ("[A] patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced." (footnote omitted)).

Thus, based on Supreme Court precedent and the treatment of product-by-process claims throughout the years by the PTO and other binding court decisions, this court now restates that "process terms in product-by-process claims serve as limitations in determining infringement." *Atl. Thermoplastics*, 970 F.2d at 846-47. As noted earlier, this holding follows this court's clear statement in *In re Thorpe* that "product by process claims are limited by and defined by the process." 777 F.2d at 697.

More recently, the Supreme Court has reiterated the broad principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson*, 520 U.S. at 19. Although *Warner-Jenkinson* specifically addressed the doctrine of equivalents, this rule applies to claim construction overall. As applied to

product-by-process claims, *Warner-Jenkinson* thus reinforces the basic rule that the process terms limit product-by-process claims. To the extent that *Scripps Clinic* is inconsistent with this rule, this court hereby expressly overrules *Scripps Clinic*.

The dissenting opinions lament the loss of a "right" that has never existed in practice or precedent -- the right to assert a product-by-process claim against a defendant who does not practice the express limitations of the claim. This court's en banc decision in no way abridges an inventor's right to stake claims in product-by-process terms. Instead this decision merely restates the rule that the defining limitations of a claim -- in this case process terms -- are also the terms that show infringement.

Thus this court does not question at all whether product-by-process claims are legitimate as a matter of form. The legitimacy of this claim form was indeed a relevant issue in the nineteenth century when *Ex parte Painter*, 1891 C.D. 200, 200-01 (Comm'r Pat. 1891), and some later cases were before the Commissioner of Patents. However, this court need not address that settled issue. The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not.

The jurisprudence of the Court of Customs and Patent Appeals -- a court with virtually no jurisdiction to address infringement litigation -- can shed little light on the enforcement of the only claim limitations that an applicant chooses to define the invention. Indeed, this court's venerable predecessor ex-

pressed its ambivalence towards the relevant infringement analysis:

> The policy of the Patent Office in permitting product-by-process type claims to define a patentable product, where necessary, has developed with full cognizance of the fact that in infringement suits some courts have construed such claims as covering only a product made by the particular process set forth in the claim and not to the product per se.

In re Bridgeford, 357 F.2d 679, 683 n.5, 53 C.C.P.A. 1182 (CCPA 1966). The reference to "some courts" in this prior citation, as this court notes en banc, includes the United States Supreme Court and every circuit court to consider the question, including this circuit. *See also* Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 530 (1960) ("[P]roduct-by-process claims have met with a most strict interpretation in the courts in infringement proceedings . . . . [T]he courts uniformly hold that only a product produced by the claim-designated process may be held to infringe the claim.") (citing *Gen. Elec. Co.*, 304 U.S. 364, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 and *BASF*, 111 U.S. at 310).

Product-by-process claims, especially for those rare situations when products were difficult or impossible to describe, historically presented a concern that the Patent Office might deny *all* product protection to such claims. *See In re Butler*, 37 F.2d 623, 17

C.C.P.A. 810, 813, 1930 Dec. Comm'r Pat. 187 (CCPA 1930) ("Process claims are valuable, and appellant thinks he is entitled to them; but it is submitted that he should not be limited to control of the process when the article which that process produces is new and useful."). In the modern context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (the subject of this case -- a product defined by sophisticated PXRD technology -- suggests that these concerns may no longer in reality exist), this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection. Because the inventor chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor.

This court's rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a product-by-process claim: "Compound X, obtained by process Y." Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder

has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?

In sum, it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made. Such a rule would expand the protection of the patent beyond the subject matter that the inventor has "particularly point[ed] out and distinctly claim[ed]" as his invention, 35 U.S.C. § 112 P 6.

Thus, the Eastern District of Virginia correctly applied the rule that the recited process steps limit the product-by-process claims 2-5 for any infringement analysis.

3. "*obtainable* by"

In this case, Abbott's plain language argument, that "*obtainable* by" introduces an optional process, even if "*obtained* by" would introduce limiting process steps, is also unavailing. The *BASF* case, an analogous situation to this case, controls. As noted above, the Supreme Court in *BASF* considered the following claim language: "Artificial alizarine, pro-

duced from anthracine or its derivatives by either of the methods herein described, *or by any other method which will produce a like result.*" *111 U.S.* at 296 (emphasis added). The patentee argued that even though the defendant did not make artificial alizarine by "either of the methods herein described," the claim should capture the product because of the "or by another method" language. *Id.* at 309. The Supreme Court refused to attach importance to those expansive words: "No. 4,321 furnishes no test by which to identify the product it covers, except that such product is to be the result of the process it describes." *Id.* at 305. Abbott's claims 2-5, like those in *BASF* and like product-by-process claims in general, do not furnish any test by which to identify the cefdinir crystals except that they are the result of their respectively claimed processes. As per *BASF*, Abbott's claim cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims.

If this court were to strip the process elements from the claims, as Abbott would urge, for infringement purposes, there would then be nothing to differentiate independent claim 2 from independent claim 5. After all, if those claims are not bound by the process terms but only "define" the basic cefdinir compound, then each of the claims recite the same thing, over and over again. Though Abbott argues that it merely intends to give meaning to the word "obtainable," it instead seeks to have this court render meaningless the explicit process limitations that the applicant chose to define its invention.

The intrinsic evidence in this case further rebuts Abbott's contention that its claims are not limited to

those products actually obtained by the processes recited. In column 2 of the '507 patent, under the title heading "The Process for Preparing Crystal A of the Compound (I)," the patentee used specific language to describe the very two processes that are mirrored in claims 2 and 5. '507 patent col.2 ll.13-51. This language is not open-ended, nor does it constitute a mere description of the product by reference to the manner in which it can be made, as Abbott argues. By drafting claims 2 and 5 to incorporate these specific processes, Abbott made a conscious choice to place process requirements on its claimed product. If Abbott had wanted to obtain broader coverage for crystalline cefdinir devoid of any process limitations, as it seeks to do here, it could have simply done so (if indeed, as it argues, it is really the product that is the heart of the invention, not the process). But it did not. The crystals of claims 2 and 5 are simply not identifiable other than by the processes disclosed in column 2. This court must enforce the ways and terms that a party chooses to define its invention.

The prosecution history also does not support Abbott's contention that "obtainable by" offers merely an optional set of definitional process conditions. During prosecution, Abbott faced obviousness rejections based on application claims 6-9, which were process claims that mirrored the *very* process limitations of issued claims 2-5. The PTO refused to issue the claims until one set of duplicates was cancelled. Abbott's action in cancelling claims 6-9 demonstrates its acquiescence to the PTO's view that the process elements of claims 2-5 are critical parts of those claims. In addition, in a response to the PTO's office action, Abbott chose to differentiate a cited §

103 reference, Takaya, on the basis that Abbott's claimed processes are different. For these reasons, the applicant's statement in the file wrapper that "the method of preparation . . . is not considered the heart of the present invention" should not be afforded undue gravitas. The process limitations cannot be haphazardly jettisoned for an infringement analysis when they were so important in the patentability analysis.

In sum, a patentee's use of the word "obtainable" rather than "obtained by" cannot give it a free pass to escape the ambit of the product-by-process claiming doctrine. Claims that include such ambiguous language should be viewed extremely narrowly. If this court does not require, as a precondition for infringement, that an accused infringer actually use a recited process, simply because of the patentee's choice of the probabilistic suffix "able," the very recitation of that process becomes redundant. This would widen the scope of the patentee's claims beyond that which is actually invented--a windfall to the inventor at the expense of future innovation and proper notice to the public of the scope of the claimed invention. For all the above reasons, the Eastern District of Virginia correctly construed the process limitations beginning with "obtainable by" in claims 2-5 as limiting the asserted claims to products made by those process steps.

B. Summary Judgment

In the *Lupin* case, the Eastern District of Virginia granted summary judgment of noninfringement of claims 2-5, both literal and by equivalents, and of claim 1 by equivalents. *Lupin SJ Order*. Lit-

eral infringement of claim 1, i.e., whether Lupin's generic cefdinir product contains any Crystal A, is therefore not a live issue on appeal. As for claims 2-5, the Eastern District noted that "Abbott and Astellas have conceded that literal infringement of Claims 2-5 cannot be established if the product-by-process analysis is performed pursuant to *Atlantic Thermoplastics*," given that "Abbott and Astellas have presented no evidence that Lupin is practicing the process steps set forth in Claims 2-5." *Lupin SJ Order*, 491 F. Supp. 2d at 568. Because the Eastern District correctly applied the rule from *Atlantic Thermoplastics* and likewise properly construed the limiting process terms in claims 2-5, only infringement by equivalents of claims 1-5 remains before this court.

Infringement analysis under the doctrine of equivalents proceeds element-by-element; a generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement. *See Warner-Jenkinson*, 520 U.S. at 29 ("the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole"). The primary test for equivalency is the "function-way-result" or "triple identity" test, whereby the patentee may show an equivalent when the accused product or process performs substantially the same function, in substantially the same way, to achieve substantially the same result, as disclosed in the claim. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608, 70 S. Ct. 854, 94 L. Ed. 1097, 1950 Dec. Comm'r Pat. 597 (1950). But, because "[d]ifferent linguistic frameworks may be more suitable to different cases," *Warner-Jenkinson*, 520 U.S.

at 40, the function-way-result test is not the only test for equivalency. Equivalency may also be proven where the differences between the invention as claimed and the accused product or process are insubstantial. *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1517-18 (Fed. Cir. 1995) (en banc), rev'd on other grounds, 520 U.S. 17, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997). In no case, however, may the doctrine of equivalents ignore the individual claim elements. *See Warner-Jenkinson*, 520 U.S. at 40 (requiring "a special vigilance against allowing the concept of equivalence to eliminate completely any such [individual] elements").

Because "crystalline" in claims 1-5 is limited to "Crystal A" as defined by the seven PXRD peaks enumerated in claim 1 and in the specification of the '507 patent, the doctrine of equivalents cannot capture crystals that are not themselves equivalent to Crystal A. In turn, the bounds of Crystal A equivalents cannot ignore the limits on Crystal A in the '507 patent, which as discussed above, includes a conscious decision to distinguish Crystal B from the claimed invention. To recall, the applicant removed Crystal B from the U.S prosecution of the parent JP '199 application. The '507 patent indisputably describes and claims Crystal A, and not Crystal B. The *'507 patent*, of course, could have claimed the known Crystal B formulation which was known to the inventors because it appeared in their priority JP '199 application. The applicants chose not to claim Crystal B. Thus Crystal B compounds, most relevantly cefdinir monohydrate, fall outside the scope, literal or equivalent, of claims 1-5 of the '507 patent.

The parties agree that the "bulk" of Lupin's cefdinir product is Crystal B, not Crystal A. The degree to which Lupin's product may or may not also contain Crystal A is the central inquiry regarding the alleged literal infringement of claim 1, which is not part of the present appeal. Abbott cannot extend its exclusive right in the '507 claims under the doctrine of equivalents to embrace known but unclaimed subject matter. In other words, Abbott effectively disclaimed Crystal B during prosecution of the '507 patent, by removing the Crystal B disclosure from the parent JP '199 application and emphasizing the sole teaching of Crystal A in communications with the PTO as well as in the '507 specification itself. Abbott cannot now recapture that unclaimed subject matter under the doctrine of equivalents because the Eastern District properly interpreted claims 2-5 to limit "crystalline" to Crystal A. To expand that claim term to embrace Crystal B would ignore the specific claim limitations of the '507 patent.

Alternatively this court notes that this case seems to fit within the dedication doctrine that forecloses invocation of the doctrine of equivalents. The patent applicant clearly knew of the Crystal B forms of the claimed invention because it claimed and disclosed them in its Japanese priority application. Yet it declined to claim an embodiment expressly disclosed in its priority document, thus dedicating that embodiment to the public and foreclosing any recapture under the doctrine of equivalents. *See Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002).

During prosecution, Abbott chose to eschew Crystal B and focus exclusively on Crystal A compounds.

Without a complete record and no arguments about validity before this court on appeal, this court cannot speculate on the reasons for this choice. Nonetheless, the parties hotly contest whether Example 14, which reports obtaining "crystals" not specifically identified or described, and/or Example 16 of the '334 patent enable cefdinir monohydrate, i.e. Crystal B type crystals.

Beyond the attempt to reinflate the claims to encompass Crystal B based on mathematical comparisons of the PXRD peak patterns of Crystal A and Crystal B, Abbott also asserts that Lupin effectively admitted infringement by equivalents when it claimed before the Food and Drug Administration that its cefdinir generic was a bioequivalent to Abbott's Omnicef product. While bioequivalency may be relevant to the function prong of the function-way-result test, bioequivalency and equivalent infringement are different inquiries. Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes. In contrast, equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product, requiring not only equivalent function but also equivalent way and result. Different attributes of a given product may thus be relevant to bioequivalency but not equivalent infringement, and vice versa. As the Northern District of Illinois observed in the *Sandoz* case, "[i]f bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent." *Sandoz PI Order*, 486 F. Supp. 2d at 776. Thus, while potentially relevant,

the bioequivalency of an accused product with a product produced from the patent at issue is not sufficient to establish infringement by equivalents.

Because Crystal B is not an equivalent of Crystal A, the Eastern District of Virginia did not err in granting summary judgment of noninfringement of claims 2-5, both with respect to literal and equivalent infringement, and with respect to equivalent infringement of claim 1.

IV.

This court reviews the grant or denial of a preliminary injunction for abuse of discretion. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). A district court may enter a preliminary injunction based on its consideration of four factors: "(1) the likelihood of the patentee's success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships between the parties; and (4) the public interest." *Erico Int'l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1353-54 (Fed. Cir. 2008) (quoting *PHG Techs., LLC v. St. John Cos., Inc.*, 469 F.3d 1361, 1365 (Fed. Cir. 2006)).

Sandoz and Teva's Omnicef generic products, like Lupin's, are also at least primarily cefdinir monohydrate, a Crystal B compound. *Sandoz PI Order*, 486 F. Supp. 2d at 769. Before the Northern District of Illinois, the parties to the *Sandoz* litigation disputed whether Sandoz and Teva's products also contained small amounts of cefdinir anhydrate, i.e., Crystal A, which would fall within the literal scope of claim 1 of the '507 patent. Working primarily from the East-

ern District of Virginia's claim construction, to which the parties to the *Sandoz* litigation agreed would bind their litigation as well for purposes of the preliminary injunction motion, the Northern District of Illinois denied Abbott's motion for a preliminary injunction, finding that Abbott was unlikely to prevail on the merits at trial.

This court detects no abuse of discretion in the Northern District of Illinois' preliminary injunction denial. As described above, the '507 patent is properly construed to exclude Crystal B, both as to literal and equivalent infringement. Thus, this court need not delve into the Northern District of Illinois' clarifications of the Eastern District of Virginia's claim constructions. The Northern District of Illinois succinctly concluded: "[w]e know that Crystal B was known to the plaintiffs because it had been included in the Japanese '199 patent. Thus we conclude that the plaintiffs deliberately excluded from the definition of Crystal A, cefdinir monohydrate, which is Crystal B." *Id.* at 775.

As to the alleged presence of small amounts of Crystal A in Sandoz and Teva's products, Abbott's evidence did not persuade the Northern District of Illinois. *Id.* This court perceives that decision as well within the trial court's discretion. As additional support, the Northern District observed that there was no evidence that any trace amounts of cefdinir anhydrate, i.e. Crystal A, in Sandoz and Teva's products "could be a contributing factor in the efficacy" and that even "if there is a small amount of cefdinir anhydrate in defendants' products, we do not conclude that this could cause literal infringement." *Id.* While these may be misstatements of the law, be-

cause *de minimis* infringement can still be infringement, *see* 35 U.S.C. § 271(a); *see also SunTiger, Inc. v. Sci. Res. Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999) ("If a claim reads merely on a part of an accused device, that is enough for infringement."), this court need not reach that issue in a preliminary injunction context which affords the trial court broad leeway to discern a "likelihood of success." Likewise the district court may have overstated the relevance of efficacy, because the '507 patent contains no claim limitations relating to efficacy. But these misstatements were harmless because they merely formed an alternative basis for the Northern District of Illinois' reasonable assessment of the evidence proffered by Abbott for its preliminary injunction motion. As noted, this court sustains the trial court's discretion based primarily on its administration of the proper claim construction and its finding that Abbott was not likely to show Sandoz and Teva's products contained any Crystal A at all.

CONCLUSION

The Eastern District of Virginia correctly construed the '507 patent's recitation of "crystalline" in each of the asserted claims as limited to Crystal A, as outlined in the specification. Because Abbott scrubbed all references to Crystal B in the '507 patent's specification, which were present in the '507 patent's parent foreign application, Abbott clearly demonstrated its intent to limit the '507 patent to Crystal A. This intent was further underscored by comments made during prosecution. As such, Abbott is unable to recapture Crystal B through broad claim language or under the doctrine of equivalents. The Eastern District of Virginia therefore properly con-

cluded on summary judgment that Lupin's cefdinir product did not infringe claims 1-5 literally or claims 2-5 by equivalency. Similarly, the Northern District of Illinois did not abuse its discretion in declining to enter a preliminary injunction against Sandoz and Teva's cefdinir products.

AFFIRMED

COSTS

Each party shall bear its own costs.

DISSENT BY: NEWMAN; MAYER; LOURIE

DISSENT

NEWMAN, *Circuit Judge*, with whom *Circuit Judges* MAYER and LOURIE join, dissenting from en banc Section III.A.2.

The court today acts *en banc* to overturn a century of precedent and practice, and holds that a new product that is difficult to describe without reference to how it was made, but that is nonetheless a new and unobvious product, cannot be protected as a product if its description is aided by reference to how it was made. Heretofore a new product whose structure was not fully known or not readily described could be patented as a product by including in the product description sufficient reference to how it can be made, to distinguish the new product from prior

art products. Patentability was determined as a product, independent of any process reference in the claim, and validity and infringement were based on the product itself. This expedient for patenting products whose structure was not fully known at the time of filing the patent application has been called the "rule of necessity." It was pragmatic, fair, and just, for it attuned patent law and practice to the realities of invention.

Today the court rejects this expedient and discards this practice, ruling that all claims containing a process term under the rule of necessity now must be construed, for purposes of infringement, as limited to use of any process term that was used to assist in defining the product. That is, such a product is not patented as a product, however it is produced, but is limited to the process by which it was obtained. This is a new restraint on patents for new products, particularly today's complex chemical and biological products whose structure may be difficult to analyze with precision. It is a change of law with unknown consequences for patent-based innovation.

The court acts *sua sponte*, without explanation of what policy is intended to be served by this change, without consideration of the technologies that may be adversely affected by elimination of this expedient, without notice to those whose property rights may be diminished. In so doing, the court departs from statute, precedent, and practice. This change is as unnecessary as it is flawed, gratuitously affecting inventions past, present, and future. I respectfully dissent.

DISCUSSION

For most product inventions, the process by which the product was made, whether or not the process is itself a patentable invention, is not stated in the product claims. However, as the variety and complexity of invention and technology have increased, various forms of product claims with process terms have been used in specific circumstances, depending on the nature of the invention.[1] The form here at issue relates to product claims for new and unobvious products whose structure is not fully known, and for which process parameters are used to aid in defining the product. This claiming expedient has been recognized since at least 1891.

The court today overturns this expedient for all circumstances, brooking no exception. Acting *en banc* for the purpose, the court rules that if any process term or descriptive aspect is included in a product claim to aid in distinguishing a new product, the claim cannot be infringed by the identical product unless the same process aspect is used in making the accused product. The court holds that it is irrelevant whether the product is new or was known, irrelevant whether the product could have been fully described by its structure at the time of the patent application, irrelevant whether the particular inven-

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[1] As discussed by Eric P. Mirabel, *Product-By-Process Claims: A Practical Perspective*, 68 J. Pat. & Trademark Off. Soc'y 3, 3-4 (1986), the various forms of product-by-process claims include "true" product-by-process claims, product claims with a process limitation, product claims with a process-derived structural element, and product claims with functional terms.

tion is a new product or is actually a process. The court adopts a simplistic universal rule, thereby targeting a small but significant class of inventions. The effect of this decision on innovation in complex fields of science and technology is unknown to the court, for we have had no advice on the consequences of this change of law. My dissent is directed as much to the court's procedure, as to the substance of the court's decision.

I. PROCEDURE

The court has given no notice of this impending *en banc* action, contrary to the Federal Rules of Appellate Procedure and contrary to the Federal Circuit's own operating procedures. The *en banc* court has received no briefing and held no argument, although the Federal Rules so require. The communities of inventors, innovators, and the public who may be affected by this change of law have had no opportunity to be heard. The court has received no information concerning the effect on patents that were granted based on this long-established practice, no advice on what kinds of inventions may now lie fallow because they are unprotected. Nor does the court explain its suspension of the standards of judicial process.

The Federal Rules have the force of law. 28 U.S.C. §2072. Federal Rules of Appellate Procedure 34 and 35 are here implicated. Rule 34 provides that "oral argument must be allowed in every case" unless certain specific exceptions exist:

> **Rule 34(a)(2) Standards**. Oral argument must be allowed in every case unless a

> panel of three judges who have examined the briefs and record unanimously agrees that oral argument is unnecessary for any of the following reasons:
>
> (A) the appeal is frivolous;
>
> (B) the dispositive issue or issues have been authoritatively decided; or
>
> (C) the facts and legal arguments are adequately presented in the briefs and record, and the decisional process would not be significantly aided by oral argument.

Applying the Rule 34 standards, it is clear that (A) this appeal is not frivolous and (B) the dispositive issue has not been authoritatively decided, for it is currently being addressed *en banc*. There has been (C) no briefing and no record to the court, and this is not a case in which the decisional process would not be aided by oral argument. The *en banc* court has heard no argument, and has received neither written nor oral exploration of the diverse aspects of this long-established claiming practice.

Federal Rule of Appellate Procedure 35 has also failed of compliance. That rule recognizes the exceptional nature of *en banc* hearing or rehearing, and identifies the two circumstances warranting such procedure:

> **Rule 35(a)** . . . An en banc hearing or rehearing is not favored and ordinarily will not be ordered unless:
>
> > (1) en banc consideration is necessary to secure or maintain uniformity of the court's decisions; or
> >
> > (2) the proceeding involves a question of exceptional importance.

When an *en banc* hearing or rehearing is ordered *sua sponte* by the court, whether for uniformity of decision or on a question of exceptional importance, the hearing or rehearing must receive the appellate process set by the Rules.

I agree that *en banc* review is appropriate, for this apparent conflict in our precedent has existed since 1992. Now that the court has undertaken to resolve the conflict, the withholding of public notice, or even notice to the parties to this case, is devoid of justification. The question is of importance, but there has been no assertion of urgency sufficient to require bypassing the standard appellate procedures. The breadth of the *en banc* court's ruling, the solidity of the precedent now overruled, the importance of the technologies affected, and the untold issued patents that are now placed in limbo, require this court's compliance with Federal Rules 34 and *35*.

The Federal Circuit has recognized that it can benefit from the advice of those knowledgeable in the

law and its purposes, in the areas of our nation-wide responsibility. Patent law has a direct impact on innovation, industry, and technological advance, and when an *en banc* ruling may change the law affecting some areas of technology and the industries based thereon, this court has routinely sought to be informed, by the parties and *amici curiae*, of relevant concerns. When the impact of a *sua sponte* change of law transcends the interests of the parties to the specific case, notice to the interested public, as well as to the parties, is fundamental to due and fair process. The Federal Circuit's Internal Operating Procedure (IOP) 14 was adopted to implement these principles:

> IOP 14.3(c) If the sua sponte petition for hearing en banc is granted, a committee of judges appointed by the chief judge, which shall normally include the judge who initiated the poll, shall within seven working days (fourteen working days between June 21 and September 11) transmit on a vote sheet to the judges who will sit en banc an order setting forth the questions proposed to be addressed by the court en banc. The clerk shall provide notice that a majority of the judges in regular service has acted under 28 U.S.C. §46 and Fed. R. App. P. 35(a) to order the appeal to be heard en banc, and indicate any questions the court may wish the parties and amici to address. Notice shall be given that the court en banc shall consist of all circuit judges in regular service who are not recused or disqualified. Addi-

tional briefing and oral argument will be ordered as appropriate.

United States Court of Appeals for the Federal Circuit, Internal Operating Procedures at 40, *available* at http://www.cafc.uscourts.gov/pdf/IOPs122006.pdf. This IOP has not been followed. No notice was given, even to the parties, that the court had ordered this question to be reheard *en banc*; nor did the court advise the parties or the public as to the aspects being addressed for *en banc* decision. The court is acting *sua sponte*, without notice and without argument and without an opportunity for participation. By bypassing this court's standard operating procedure, as well as violating the Federal Rules of Appellate Procedure, the court has deprived itself of input concerning the experience of precedent, of advice as to how this change of law may affect future innovation, and of guidance as to the effect on existing property rights.

II. PRECEDENT AND PRACTICE

The court's opinion does not mention the long-established precedent that it is overturning. This is not a simple conflict between isolated rulings of the Federal Circuit; it is a change of law and practice with roots in century-old decisions. I start with this precedent, for the expedient of what came to be called the "rule of necessity" originated in the recognition, by the courts and the Patent Office, that not all new products could be fully described by their structure, due to the state of scientific knowledge or available analytical techniques. It was also recognized, over a century ago, that sufficient distinction

from prior art products could sometimes be achieved by reference to how the product was made. Thus the courts and patent administrators established the exception that permitted inclusion in a product claim of sufficient recitation of how the product was made, to aid in identifying the product and distinguishing it from the prior art. This claim form was loosely called a "product-by-process" form, although that term includes a variety of situations, *see* n.1 *supra*, having diverse legal consequences. The only form here at issue is that in which the product is new and its structure is not fully or readily known, such that its definition as a product is aided by referring to how it was made. Since before 1891, this has been an accepted way to claim products as products, recognizing that this is an exception to the general rule that new products are claimed without reference to the process by which they are produced.

This exception was discussed in 1891 in *Ex parte Painter*, the Commissioner of Patents explaining that when there is entitlement to a patent on a new article of manufacture, it can be claimed by reference to the process of producing it, when the inventor lacks other language to "define and discriminate" the invention:

> It requires no argument to establish the proposition that *as a rule* a claim for an article of manufacture should not be defined by the process of producing that article. On the other hand, when a man has made an invention his right to a patent for it, or his right to a claim properly defining it, is not to be determined by the

> limitations of the English language. When the case arises that an article of manufacture is a new thing, a useful thing, and embodies invention, and that article cannot be properly defined and discriminated from prior art otherwise than by reference to the process of producing it, a case is presented which constitutes an exception to the rule.

1891 C.D. 200, 200-01 (Comm'r Pat. 1891). The Commissioner cited, as an earlier example of this exception, the claim in *Globe Nail Co. v. U.S. Horse Nail Co.*, 19 F. 819 (C.C.D. Mass. 1884) (sustaining validity of claim directed to horse-shoe nail claimed by reference to its process of manufacture, and finding it infringed by the accused nail having only a "trivial and unsubstantial variation" from the claimed product). In contrast, where the patent application made clear that the product could be described by its structure, the Patent Office ruled that the exception did not apply. *See, e.g., Ex parte Scheckner*, 1903 C.D. 315, 315-16 (Comm'r Pat. 1903) (sustaining rejection of claim directed to an etched printing-plate that "specifies certain steps by means of which the etching is accomplished" because other claims "define the plate in terms of its structure").

This expedient has been discussed in various judicial decisions. In all cases the issue has not been whether this expedient was available, for its availability was not challenged; the issue was simply its application to the particular facts. For example, at a time when it heard direct appeals from Patent Office

rulings, the D.C. Circuit remarked on this "only exception" to the general rule of product claiming, stating:

> It is a well-settled rule of patent law that claims for a product which is defined by the process of producing it will not be allowed; and the only exception to this rule seems to be in cases where the product involves invention and *cannot be defined except by the process used in its creation.* In extreme cases of this character, the product may be allowed; but that is not this case, especially in view of the broad claims allowed appellant in his copending application . . . .

In re Brown, 29 F.2d 873, 874, 1929 Dec. Comm'r Pat. 164 (D.C. Cir. 1928) (emphasis added).

The Court of Customs and Patent Appeals discussed precedent involving claims for processes and products in various factual situations, and summarized that:

> Where it is possible to define a product by its characteristics, the practice is clearly settled that this should be done. Where, however, the product is novel and involves invention and *cannot be defined except by the steps of the process involved in its creation*, there are cases holding that such a claim may be allowed, and it has been sustained by a Court.

In re Butler, 37 F.2d 623, 626, 17 C.C.P.A. 810, 1930 Dec. Comm'r Pat. 187 (CCPA 1930) (emphasis added) (quoting *Ex Parte Feisenmeier*, 1922 C.D. 18 (Comm'r Pat. 1922)). The CCPA then found this rule inapplicable to the facts of Butler's invention, explaining that "the record at bar does not meet this requirement [that the product was new]." *Id.*

In *In re Lifton,* 189 F.2d 261, 38 C.C.P.A. 1119, 1951 Dec. Comm'r Pat. 438 (CCPA 1951), the CCPA again commented on this exception for product claims, stating that when "proper article claims" were possible they must be used, with the exception of when such claims are "impossible":

> This court has uniformly held that a claim for an article must define the article by its structure and not by the process of making it. The one exception to this rule, where the invention is the article and *it is impossible to otherwise define it,* is clearly ruled out in the present case be cause appellant has demonstrated the possibility of proper article claims by including several devoid of process limitations.

Id. at 263 (emphasis added, citations omitted). The court again recognized "the one exception," holding once again that it does not apply when the product can be described independently of the process of making it.

These inquiries into the facts warranting application of the exception demonstrate that the rule of ne-

cessity was seldom applied, but was nonetheless recognized both by the courts and the Patent Office. Decisions of the Patent Office Board of Appeals illustrate the practice. *See, e.g., Ex parte Pfenning, 65 U.S.P.Q. 577 (Pat. Off. Bd. App. 1945)* (allowing claim "directed to a product which results from the method of claim 9" in light of applicant's argument that "it is impossible in the instant case to define the product adequately in terms of the elements which compose it or in terms of its physical characteristics"); *Ex parte Lessig, 57 U.S.P.Q. 129 (Pat. Off. Bd. App. 1943)* (allowing claim for a "product containing vulcanized rubber" strongly adhered to fibers which "has been prepared by the process of claim 4" because "it is not possible to otherwise distinguish over the art of record").

Commentators have explained that this claiming practice became of increasing importance as the complex sciences blossomed. *See, e.g.*, Mark D. Passler, *Product-by-Process Patent Claims: Majority of the Court of Appeals for the Federal Circuit Forgets Purpose of the Patent Act, 49 U. Miami L. Rev.* 233, 233 n.3 (1994) ("Such claims are often used by companies to patent complex drug or chemical products whose structure is not completely understood and, therefore, can only be accurately described by the process through which it is made."). It is well known that the full structure of some chemical and biological products is not always known at the time the patent application is filed. Indeed, it is a tenet of the scientific method that explanation and theory tend to follow, not precede, the observation of a development in the science.

The CCPA continued to recognize the use of process terms to aid in describing new products--the form of claim sometimes called a "pure" product-by-process claim, *see* n.1 *supra*--and repeatedly ruled that such claims are properly viewed as product, not process, claims. The court also disallowed such claims where the product itself was not novel and unobvious. The court confirmed that such a claim, when justified for a novel and unobvious product, is properly construed as encompassing the full scope of a product claim. For example, in *In re Bridgeford*, 357 F.2d 679, 53 C.C.P.A. 1182 (CCPA 1966), the court again explained that a new product may be defined by the process of making it if there is no other way to describe the product, stressing that "the invention so defined is a product and not a process," *id.* at 682. The *Bridgeford* court relied on this view of the scope of the product-by-process claims in a related patent, and held unpatentable for double patenting claims that defined the "product per se." *Id.* at 680. The court explained that product-by-process claims are true product claims, and overruled the suggestion in *In re Freeman*, 166 F.2d 178, 181, 35 C.C.P.A. 920, 1948 Dec. Comm'r Pat. 276 (CCPA 1948), that product-by-process claims are "dependen[t] . . . on process limitations" and therefore coextensive with process claims. *Bridgeford*, 357 F.2d at 683 n.6 ("While there is some language in *Freeman* to support the contention that a product-by-process type claim differs only 'in scope' from a process type claim and they therefore 'are directed to a single invention,' (166 F.2d at 181) so far as this is inconsistent with our holding here it must be overruled.").

My colleagues misstate the holding of *Bridgeford*, for *Bridgeford* directly contravenes today's holding. In *Bridgeford* the CCPA noted that "some courts" have construed claims with process steps as limited to the recited process, *id.* at 683 n.5, apparently without inquiring whether the rule of necessity justified full product scope for the invention at issue. The CCPA's observation that patents are construed inconsistently in other courts cannot be taken, as apparently do my colleagues, as error by the CCPA. To the contrary, the inconsistency among courts led eventually to consolidation.[2]

Again in *In re Brown*, 459 F.2d 531, 59 C.C.P.A. 1036 (CCPA 1972), the CCPA explained that product-by-process claims are product claims, not process claims, and that the patentability of the product must be established independently of the process by which it is identified. *See id.* at 535 ("[I]n spite of the fact that the claim may recite only process limitations, it is the patentability of the *product* claimed and *not* of the recited process steps which must be established.").

Other decisions discussing application of this expedient to claims directed to complex new products include *In re Pilkington*, 411 F.2d 1345, 1349, 56 C.C.P.A. 1237 (CCPA 1969) ("While we are satisfied

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[2] The Hruska Commission Report, which informed the debate that eventually led to the formation of our court, described the varying attitudes towards patents held by the regional courts of appeal and the variations in patent rulings among the circuits. *See Commission on Revision of the Federal Court Appellate System Structure and Internal Procedures: Recommendations for Change*, 67 F.R.D. 195, 370 (1975).

that the references of record do not anticipate appellant's glass or demonstrate that it would be obvious, the differences between that glass and the glass of the prior art do not appear to us to be particularly susceptible to definition by the conventional recitation of properties or structure."), and *In re Fessmann*, 489 F.2d 742, 743 (CCPA 1974) (affirming obviousness rejection of product-by-process claim directed to a "liquid smoke" product, but observing that prior art compositions "are complex mixtures of the chemical compounds which can be derived from wood" which "defy simple characterization and this fact presumably accounts for the use of product-by-process claims"). The need for this expedient, and the proper scope afforded such claims, is summarized in the treatise *Walker on Patents*:

> [P]atent rights over a chemical product are typically independent of the process by which the product is made, and are particularly valuable because of this fact. This independence is normally accomplished by defining the product in terms of its structural features alone, with no reference in the claims to process steps whatsoever. *The state of chemical technology, however, is sometimes too limited for a structural description of this type to be made.* The structure of some chemicals, especially those including elaborate polymer chains, cannot be accurately determined. The same chemicals, however, may be both economically valuable and technologically reproducible, in the sense that they can be reliably made by subject-

> ing a particular set of raw materials to a particular set of process steps.
>
> * * *
>
> The law reacted to these difficulties by making it easier to obtain traditional product protection over this special class of chemicals. The inventor was allowed to describe such a chemical in terms of how one gained possession of it, that is, by way of the process steps by which it was made. Once he did so, the law preserved to the inventor the fullest measure of product-only protection that it could; *it treated the process recitations as proxies for the direct recitations of structure that could not be made.* Such a claim was therefore equivalent to one stated in terms of structure only. It would broadly dominate all methods by which the chemical could be made or used. At the same time, it carried the same dangers of running afoul of the art: it would be anticipated if the chemical had been produced previously, even if by a method other than what the inventor disclosed.

1 *Moy's Walker on Patents* §4:74 (4th ed. 2008) (emphases added).

The *en banc* court appears to misunderstand this precedent, for my colleagues now state that "binding case law" of the Court of Customs and Patent Appeals and the Court of Claims mandates a single rule for all claims that contain any process terms,

whether the product is novel or known, citing *In re Hughes*, 496 F.2d 1216 (CCPA 1974), for this proposition. However, *Hughes* does not state this proposition; *Hughes* stands for the contrary proposition. In *Hughes* the question was the patentability of claims directed to "shakes" as are used in roofing, as follows:

> 12. Shakes manufactured from a shake bolt by the process of making a plurality of cuts into and across the shake bolt to an extent to establish predetermined tip lengths, and splitting the weather end portions of the shakes from the bolt by starting the splits at the inner ends of the cuts and continuing the splits to the end of the bolt.

This claim had been rejected as an improper product-by-process claim, on the ground that the product could be described without including process steps. The *Hughes* court acknowledged the general rule against product-by-process claiming, but also explained the "proper exception to the general rule" as first set forth in *Painter*, as follows:

> [T]he Commissioner of Patents enunciated the general rule that a product should not be defined in terms of the process of making it. In *Painter*, a proper exception to the general rule was found on the ground that the product could not be properly defined and discriminated from the prior art otherwise than by reference to the process of producing it. This basic

> rule and the exception have been recognized and followed continuously by the Patent Office and the Courts.

Hughes, 496 F.2d at 1218 (quoting approvingly the Solicitor's argument). The court reaffirmed that "in spite of the fact that a product-by-process claim may recite only process limitations, 'it is the product which is covered by the claim and not the recited process steps.'" *Id.* Contrary to my colleagues' statement, *Hughes* did not eliminate this form of claim, or change its role as a product claim. Indeed, the *Hughes* court applied the exception and reversed the Board's rejection of a product-by-process claim, stating:

> We agree with appellant that the [general] rule should not be applied to the situation before us. We have been shown no true product claim which describes appellant's invention, in the words of the solicitor, "in terms of structure or physical characteristics." When an applicant seeks to describe his invention by a product-by-process claim because he finds that his invention is incapable of description solely by structure or physical characteristics, it is incumbent upon the Patent Office to indicate where, or how, the applicant's invention is, or may be, so described.

Id. at 1219. My colleagues could hardly have selected less apt support for their construction of product-by-process claims, for *Hughes* explicitly states that such claims are for the product, not the process.

In addition to misstating precedent of the CCPA, the *en banc* court also mischaracterizes the decisions of our predecessor the Court of Claims, stating that the Court of Claims' decisions support today's ruling. The court cites *Tri-Wall Containers v. United States,* 408 F.2d 748, 187 Ct. Cl. 326 (Ct. Cl. 1969), for this purpose. That citation, too, is mysterious, for in *Tri-Wall Containers* the court found that the claimed product was not "new" because it had been on sale for more than the permitted period, although the product that was on sale had been made by a different process than the process stated in the claim. The Court of Claims stated that the evidence showed that "the prior art product and the claimed product are structurally identical," *id.* at 751, and explained that a known product cannot be patented by including process terms in the claim:

> It is well established that a product claimed as made by a new process is not patentable unless the product itself is new. *The Wood-Paper Patent,* 90 U.S. (23 Wall.) 566, 596, 23 L. Ed. 31 (1874), *Cochrane v. Badische Anilin & Soda Fabrik ["BASF"],* 111 U.S. 293, 311, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1984). . . .
>
> . . . .
>
> More recent cases point out that the addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product. *Jungersen v. Baden,* 69 F. Supp. 922, 928

(D.C.S.D.N.Y. 1947), aff'd, 166 F.2d 807 (2d Cir. 1948), aff'd, 335 U.S. 560, 69 S. Ct. 269, 93 L. Ed. 235 (1949); *In re Stephens,* 345 F.2d 1020, 1023, 52 CCPA 1409, 1965 Dec. Comm'r Pat. 707 (1965).

Tri-Wall Containers, 408 F.2d at 750-51. This case applied the standard rule that old products cannot be patented--it contains no statement limiting the scope of claims that include process aspects to aid in describing new products. The Supreme Court cases cited in *Tri-Wall* are all directed to new processes for making old products--these are the same cases that the *en banc* court today incorrectly applies to new products, as I discuss *post.*

Contrary to my colleagues' statement, CCPA and Court of Claims precedent do not support today's *en banc* thesis. Our predecessor courts understood the complexity of patenting, and the CCPA consistently implemented the expedient whereby process terms contributed to the description of complex new products of incompletely known structure. These courts recognized the independence of product claims for new products, and did not limit such claims to the specific process steps that were used to aid in describing the product.[3]

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[3] The en banc court impugns the CCPA's experience. Maj. op. at 18 (stating that the CCPA had "virtually no jurisdiction to address infringement litigation"). The CCPA for many years addressed infringement litigation, in appeals from the International Trade Commission and its predecessor tribunals. *E.g., Sealed Air Corp. v. Int'l Trade Comm'n,* 645 F.2d 976, 68 C.C.P.A. 93 (CCPA 1981) (issues of validity and infringement); *Hale Fire Pump Co. v. Tokai, Ltd.,* 614 F.2d 1278, 67 C.C.P.A.

With the advent of the Federal Circuit, this court continued to apply these principles. In *In re Thorpe*, 777 F.2d 695 (Fed. Cir. 1985), the court explained that product-by-process claims are anticipated when the product existed in the prior art, even if the product was made by a different process. My colleagues are mistaken in stating that *Thorpe* held that all such claims are to be construed as process claims, even when the product is new and the rule of necessity justifies this mode of describing the invention. In *Thorpe* the product was not new; it was a known color developer for carbonless paper copy systems, and this court held that the PTO correctly rejected the claim to "the product of the process of claim 1," explaining that since the product was old it could not be claimed as a product, whether or not process steps are recited in the claim.

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121 (CCPA 1980) (issues of validity, scope, and infringement); *In re Orion*, 71 F.2d 458, 22 C.C.P.A. 149, Treas. Dec. 47123, T.D. 47123 (CCPA 1934) (issues of jurisdiction and infringement).

Our predecessor's legal and scholarly distinction in the field of patent law, and the high regard in which Congress and the innovation communities held the jurisprudence of the CCPA were a critical foundation for formation of the Federal Circuit and its charge to reinvigorate the role of the patent system in service to the nation's technological innovation. *See* 125 Cong. Rec. 23,462 (1979) (statement of Sen. DeConcini) ("It is a reflection of high esteem which Congress has for the sitting judges of the Court of Claims and Court of Customs and Patent Appeals that these judges will become the first judges of the new Court of the Federal Circuit.").

The facts of *Thorpe* did not concern the exception and expedient where process terms are invoked to describe a new product of complex structure. This exception is rarely invoked. The general rule requiring claims to have a process-free definition of the structure of a new product accommodates most inventions. Some recent exceptions are seen in emerging aspects of biotechnology. For example, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 706 F. Supp. 94 (D. Mass. 1989), aff'd in relevant part, 927 F.2d 1200 (Fed. Cir. 1991), the district court considered the following claim:

> 4. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 1, 2 or 3 in a manner allowing the host cell to express erythropoietin.

Id. at 108. The district court found claim 4 "ambiguous," explaining that while it is directed to a new product--this host cell--the words "transformed or transfected" appear to invoke a process. The district court recognized that "[i]n the traditional patent framework, a product is wholly separate and distinct from a process." *Id.* at 107. The court observed that "[a] product patent gives the patentee the right to restrict the use and sale of the product regardless of how and by whom it was manufactured," while "[a] process patentee's power extends only to those products made by the patented process." *Id.* (quoting *United States v. Studiengesellschaft Kohle*, 670 F.2d 1122, 1127-28, 216 U.S. App. D.C. 303 (D.C. Cir. 1981)). The district court, affirmed by the Federal Circuit, found this claim to be

valid and infringed as a product claim, and although many issues and arguments were present in this litigation, the applicability of the venerable rule of necessity was not at issue.

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991), the Federal Circuit addressed the interpretation and scope of claims exemplified by claim 13:

> 13. Highly purified and concentrated VIII:C prepared in accordance with the method of claim 1.

Claim 1 set forth the method referred to in claim 13, as follows:

> 1. An improved method of preparing Factor VIII procoagulant activity protein [VIII:C] comprising the steps of
>
> (a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,
>
> (b) eluting the VIII:C,
>
> (c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,
>
> (d) eluting the adsorbed VIII:C, and
>
> (e) recovering highly purified and concentrated VIII:C.

It was not disputed that the product was a new product, that the "highly purified and concentrated" blood clotting Factor VIII:C had not previously been obtained, and that a complete structural identification of Factor VIII:C was not available. The defendant Genentech had made its commercial Factor VIII:C not by the method set forth in claim 1, but by using a sample of the Scripps product to "clone" Factor VIII:C protein using recombinant DNA techniques. One question presented in the case was whether claims such as claim 13 were infringed by the same product produced by a different method, or whether such claims were infringed only if the accused infringer used the process of claim 1.

Scripps stressed that its product was novel and enabled and was patentable as a product, although the full structure of Factor VIII:C was not available at that stage of the science. The court addressed whether claims exemplified by claim 13, properly construed, were product claims, or whether they were limited to the specific processes in the process claims to which they referred. This court held that the claims were product claims. The court held that since claims are construed the same way for infringement as for validity, the question was whether the Genentech product was the same as the claimed product, not whether they were produced by the same process. The court remanded to the district court for this factual determination. *Scripps*, 927 F.2d at 1584.

After *Scripps* was decided, a panel of this court decided an appeal concerning plastic innersoles for shoes. In *Atlantic Thermoplastics Co. v. Faytex*

Corp., 970 F.2d 834 (Fed. Cir. 1992), the claims at issue were represented by:

Claim 24. The product produced by the method of claim 1.

In turn, claim 1 was as follows:

> 1. In a method of manufacturing a shock-absorbing, molded innersole for insertion in footwear, which method comprises:
>
> (a) introducing an expandable, polyurethane into a mold; and
>
> (b) recovering from the mold an innersole which comprises a contoured heel and arch section composed of a substantially open-celled polyurethane foam material, the improvement which comprises:
>
> (i) placing an elastomeric insert material into the mold, the insert material having greater shock-absorbing properties and being less resilient than the molded, open-celled polyurethane foam material, and the insert material having sufficient surface tack to remain in the placed position in the mold on the introduction of the expandable polyurethane material so as to permit the expandable polyurethane material to expand about the insert material without displacement of the insert material; and
>
> (ii) recovering a molded innersole with the insert material having a tacky surface

> forming a part of the exposed bottom surface of the recovered innersole.

The panel held that a claim in the form of claim 24 always requires use of the referenced method, and that it is irrelevant whether the product was new or known. The court stated that the rule of necessity, as applied in *Scripps*, is contrary to Supreme Court rulings. The panel stated that the decision in *Scripps* is incorrect. A majority of the Federal Circuit declined to resolve the conflict *en banc*, resulting in several further opinions. *E.g., Atlantic Thermoplastics Co. v. Faytex Corp.*, 974 F.2d 1279 (Fed. Cir. 1992) (dissents of Chief Judge Nies and Judges Rich, Newman, and Lourie from denial of rehearing *en banc*). Judge Rich wrote:

> [T]his whole excursion was unnecessary because the patentee admitted that claim 24, the product-by-process claim, was limited to the process. The claim read: "The molded innersole produced by the method of claim 1." There was, therefore, no occasion to review the law to determine how the claim should be construed. . . . We are not here to provide restatements of the law. Such restatements should not be made without an opportunity for all affected parties to be heard from. The affected parties here are not the vendors of inner soles but largely the entire chemical industry, particularly the pharmaceutical manufacturers.

Id. at 1280 (Rich, J., dissenting from denial of rehearing *en banc*).

Most trial courts continued to recognize the rule of necessity. For example, in *Trustees of Columbia University v. Roche Diagnostics GmbH,* 126 F. Supp. 2d 16 (D. Mass. 2000), the district court considered claims such as the following.

> 72. A eukaryotic cell into which foreign DNA I has been inserted in accordance with the process of claim 54.

The court referred to the *Scripps/Atlantic* conflict, concluded that the earlier panel decision controlled under the Federal Circuit's rule, *see Newell Companies, Inc. v. Kenney Manufacturing Co.,* 864 F.2d 757, 765 (Fed. Cir. 1988) ("This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *in banc*."), and applied the *Scripps* ruling, holding that the new cell was not limited by the process by which it was made.

The PTO also continued to apply the rule of necessity. In instructing examiners that products should whenever possible be described without reference to how they were made, the PTO continued to point out the exception that patentability as a product is not foreclosed when independent description is not available. The Manual of Patent Examining Procedure (MPEP) instructs the examiner to consider the structure implied by any process steps in the claim:

> The structure implied by the process steps should be considered when assessing the patentability of product by process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.

MPEP §2113 (8th ed., July 2008 rev.). This has been the practice since at least *Ex parte Painter* in 1891. I am surprised at the *en banc* court's casual misstatement about "the treatment of product-by-process claims throughout the years by the PTO," maj. op. at 17, for the statement is directly contrary to the treatment of such claims throughout the years by the PTO.

The *en banc* court's insistence that one universal rule should now be applied is contrary to the entire body of decisional law, including the Supreme Court cases cited by my colleagues. As I next discuss, in most of the cited cases the product was not a new product and thus was not patentable as a product, whether or not any process term was included in the claim. The Court consistently held that when the product was old and only the process was a patentable invention, a claim for the "product of that process" could not cover the old product made by a different process. That is, and has always been, the law. I comment briefly on the Court's cases that my colleagues misinterpret and misapply:

Cochrane v. BASF

The *en banc* opinion relies primarily on *Cochrane v. Badische Anilin & Soda Fabrik,* 111 U.S. 293, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884) ("BASF"), even though my colleagues acknowledge that the product in that case was the well-known dye alizarine. The patent before the Court was a reissue patent that claimed artificial alizarine in the following way:

> Artificial alizarine, produced by either of the methods herein described, or by any other method which will produce a like result.

The Court held that since alizarine was a known product, the claim was limited to the patentee's two processes, stating:

> It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction from being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared, artificially, for the first time, from anthracite, if it was set forth as alizarine, a well-known substance. *Wood Paper Patent, 23 Wall. 566, 593 [(1874)]*. There was therefore no foundation for *reissue No. 4,321*, for the product,

> because, on the description given, no patent for the product could have been taken out originally.

111 U.S. at 311-12. The Court accordingly limited the claim to the two processes described in the patent, and in the portion of *BASF* quoted by my colleagues, the Court discussed the proofs needed to show infringement:

> [U]nless it is shown that the process of [the specification] was followed to produce the defendants' article, or unless it is shown that the article could not be produced by any other process, the defendants' article cannot be identified as the product of the process of [the specification]. Nothing of the kind is shown.

Id. at 310. The Court did not state, or imply, despite my colleagues' contrary theory, that a claim to a new and complex product that is of necessity defined and distinguished by the process by which it was made, can never be infringed unless that specific process is practiced. There was no issue in *BASF* of a product that could not be defined without reference to how it was made. The *BASF* Court, providing guidance, remarked on the importance of independent description of a patented product, in the following sentence cited by my colleagues:

> Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing

> can be held to infringe the patent which is not made by that process.

Id. at 310. This statement is indeed the general rule, as stated by the Patent Commissioner several years later in *Ex parte Painter*. However, *BASF* did not present the situation for which the expedient of necessity was created, for as the Court stated, the invention was "a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent, and is the process of preparing the known product alizarine from anthracine." *Id.* at 308-09.

This was not an instance of a new product describable only in terms of its process of manufacture. The *BASF* decision lends no support to today's *en banc* rule that every product claim that mentions a process step is always restricted to that process, with no exception, no expedient, no preservation of the distinctions among forms of claim based on the nature of the invention.

The Goodyear Dental cases

The *en banc* court also states that its new ruling is supported by two cases relating to a patent on the use of vulcanized rubber to form a plate for holding dentures, *Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. (3 Otto) 486, 23 L. Ed. 952, 1877 Dec. Comm'r Pat. 171 (1876), and *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. (12 Otto) 222, 26 L. Ed. 149, 1881 Dec. Comm'r Pat. 131 (1880). Review of these

cases reveals no support for the *en banc* court's statement of their holdings. The claim at issue was:

> The plate of hard rubber or vulcanite, or its equivalent, for holding artificial teeth, or teeth and gums, substantially as described.

Davis, 102 U.S. (12 Otto) at 223. The claim was written in the then-standard format of incorporating the description in the specification through the phrase "substantially as described." This was not a product-by-process or product-of-the-process claim at all, for the claim contains no process distinction or limitation, but simply refers to the description in the specification. Nonetheless, the *en banc* majority appears to state that these cases mean that the Supreme Court requires that all claims for products whose method of production is set forth in the specification--as is required by the description and enablement requirement--cannot be infringed unless that method is used.

That is not what the *Goodyear Dental* cases said. The Court referred to the position of Goodyear Dental Vulcanite that its patent covered all dental plates made of vulcanized rubber, and held, upon reviewing the specification and the prior art, that the process of manufacture was what distinguished this dental plate from the prior art dental plates, and concluded: "The invention, then, is a product or manufacture made in a defined manner. It is not a product alone, separated from the process by which it is created." *Smith*, 93 U.S. (3 Otto) at 493. Were the claim not limited to this process, the Court concluded that the

claim would not have been patentable. *See id.* at 492 (holding that if the patent were for a "mere substitution of vulcanite for other materials, which had previously been employed as a base for artificial sets of teeth" then it "constituted no invention"). Four years later, considering the same patent in *Davis*, the Court emphasized that the claim was limited to use of vulcanized rubber or its equivalent, and held that since the accused infringer made its dental plate with celluloid, there could not be infringement. *See* 102 U.S. (12 Otto) at 228-30.

The court today cites these cases as definitive of the interpretation of claims with process elements, although the only process referent is the phrase "substantially as described." This flawed reasoning was disposed of in 1890 in the classic *Robinson on Patents*, and until now has not reappeared:

> In stating Claims certain phrases are frequently employed to which a special importance seems to be attached by applicants. Among these are the phrase "substantially as described" and others of the same meaning. These phrases import the same thing when used in a Claim as when elsewhere employed. They are neither necessary nor technical. The reference they make to the Description is always implied, and relates only to the essential features of the invention as therein delineated. They add nothing, therefore, to the certainty of the Claim, nor do they detract from it unless the claimant carelessly inserts them as a substitute for a

> more clear and definite statement of his invention.

II W.C. Robinson, *Robinson on Patents* 517 (1890) (footnotes omitted).

Merrill v. Yeomans

My colleagues also rely on *Merrill v. Yeomans,* 94 U.S. (4 Otto) 568, 24 L. Ed. 235, 1877 Dec. Comm'r Pat. 279 (1877). Again, the relevance is remote. The *Merrill* Court explained that the issue was the "correct construction of plaintiff's patent," *id.* at 569, construing the following claim:

> [T]he above-described new manufacture of the deodorized heavy hydrocarbon oils, suitable for lubricating and other purposes, free from the characteristic odors of hydrocarbon oils, and having a slight smell like fatty oil, from hydrocarbon oils, by treating them substantially as hereinbefore described.

Id. at 570. The Court examined the specification to determine what was invented, and found that the invention was directed solely to a process, not to a product. The Court then concluded that the claim's usage "new manufacture" referred to the manufacturing process, and not to the product. The claim was thus a process claim, and no "product-by-process" issue was presented. The Court concluded that the defendant's oil, which was made by a different process, did not infringe.

The *Merrill* Court discussed its practice of looking to the patent application and interpreting the claim in light of what was "really invented":

> [W]here it appears that a valuable invention has really been made, this court, giving full effect to all that is found in the application on which the Patent Office acted, will uphold that which was really invented, and which comes within any fair interpretation of the patentee's assertion of claim.

Id. at 573. This approach is inimical to the *en banc* court's theory that it is irrelevant what the patentee describes as his invention, and that if a process step is mentioned in the claim or "substantially described" in the specification, the claim always requires performance of that step. Although the Court in *Merrill* was not confronted with a situation of indescribable product or necessity bred of complexity--indeed no product at all was claimed--neither did the Court hold that every product invention must be limited by the process that produced the product.

The Wood Paper Patent case

The list of Supreme Court cases relied on by my colleagues continues with *The Wood Paper Patent, 90 U.S. 566, 596, 23 L. Ed. 31 (1874)*, where claims with the standard "substantially as described" language were construed in two reissue patents relating to the pulping of wood to make paper. The Court explained that one reissue patent was for "a product or manufacture, and not for the process by which the product may be obtained," and the other "for a proc-

ess and not for its product." *Id.* at 593. The Court examined the prior art and concluded that the claim for the product could not be sustained, because the product produced by the inventor's new pulping process was not new:

> Paper-pulp obtained from various vegetable substances was in common use before the original patent was granted to Watt & Burgess, and whatever may be said of their process for obtaining it, the product was in no sense new. The reissued *patent, No. 1448*, is, therefore, void for want of novelty in the manufacture patented.

Id. at 596. The Court then discussed the reissue patent for the "process and not for its product," and held this reissue void because it claimed a different invention than in the original patent. The Court also discussed several other patents directed to boilers used to produce paper-pulp, and to a process for bleaching straw. Nothing in this case concerns the product-by-process issue on which the court is today acting.

I cannot discern why the *en banc* court relies on *The Wood Paper Patent* case as invalidating *Scripps*, and the court has not attempted to explain.

Plummer v. Sargent

The *en banc* court also relies on *Plummer v. Sargent*, 120 U.S. 442, 7 S. Ct. 640, 30 L. Ed. 737 (1887), which again provides no support for my colleagues' thesis. This case again illustrates the Court's practice of reviewing what the patentee stated he in-

vented as set forth in the specification in light of the prior art. The claim in *Plummer* was for a "new manufacture," "substantially as described":

> What I claim and desire to procure by letters patent is the new manufacture hereinabove described, consisting of iron ornamented in imitation of bronze by the application of oil and heat, substantially as described.

Id. at 445. The trial court had found non-infringement because the defendant had used a prior art process for bronzing iron. This prior process was work of F.W. Brocksieper, an employee of the defendant's predecessor company. The Supreme Court affirmed, stating that the claims were limited to the process described in the specification:

> It seems necessarily to follow from this view either that the Tucker patents are void by reason of anticipation practiced by Brocksieper, or that the patented process and product must be restricted to exactly what is described . . . .

Id. at 449. The Court thus limited the claims to the process described by the patentee, not because of any rule about limiting a product to how it was made in the specification, but to sustain validity of the patent in view of the Brocksieper prior art. The decision in *Plummer* is unrelated to any rule of claim construction based on whether process terms are included in the claim.

These nineteenth-century cases do not relate to the *en banc* court's new universal rule of claim construction, whereby all product claims having process terms are treated as process claims, whatever the nature of the product, whatever the need for process descriptors, or any other factor that precedent shows to be relevant to the exception that is here at issue as to the use of and construction of such claims. Nor do any more recent Court cases.

General Electric v. Wabash

My colleagues also cite *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 58 S. Ct. 899, 82 L. Ed. 1402, 1938 Dec. Comm'r Pat. 813 (1938), although the relevance of this case is, again, not apparent, for it involved no product-by-process claims, but rather claims that recite the properties of the product. A typical claim is claim 25, which describes an electric lamp filament composed of tungsten grains of a size and shape that prevents sagging of the filament:

> 25. A filament for electric incandescent lamps or other devices, composed substantially of tungsten and made up mainly of a number of comparatively large grains of such size and contour as to prevent substantial sagging and offsetting during a normal or commercially useful life for such a lamp or other device.

Id. at 368. The Court held this claim "invalid on its face" for failing to provide a "distinct and definite statement of what he claims to be new, and to be his invention." *Id.* at 369. The Court stated that the de-

scription of the grains as "of such size and contour as to prevent substantial sagging and offsetting" was "inadequate as a description of the structural characteristics of the grains." *Id.* at 370. The Court also criticized the use of functional language in the claim, stating that such terms were too indefinite to provide clear guidance. *Id.* at 371. There was no issue of whether process steps in the claims were regarded as limiting, for there were no process steps in the claims. Instead, the Court stated that even the implicit inclusion of process steps could not save the claim, because the description of the process in the specification was inadequate:

> Even assuming that definiteness may be imparted to the product claim by that part of the specification which purportedly details only a method of making the product, the description of the Pacz process is likewise silent as to the nature of the filament product.

Id. at 373. The Court held the patent invalid for lack of a "distinct and definite" description of the invention, for the court "doubted whether one who discovers or invents a product he knows to be new will ever find it impossible to describe some aspect of its novelty." *Id.* Whatever the inadequacies in the Pacz description of his invention, the Court's optimistic view of scientific capability cannot be deemed to have barred all recourse to the rule of necessity when it is warranted, or to have voided the ensuing seventy-one years of Patent Office and judicial recognition of this pragmatic expedient.

No Supreme Court case discussed the problems of complexity and structural analysis that warrant this expedient, or created a legal solution to these problems. It is inappropriate, unsupported by law or precedent, and contrary to the purposes of patent systems, for this court now to rule that such products cannot be patented as products.

Regional circuit decisions

My colleagues also rely on some decisions of the regional circuits preceding this court's formation, announcing that "our sister circuits also followed the general rule that the defining process terms limit product-by-process claims," and citing two cases, one decided in 1915 and one in 1977. These cases do not support the *en banc* court's opinion,[4] and raised no issue of an expedient based on necessity.

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[4] It is curious to observe this en banc court extolling decisions of the regional circuits as authoritative, while it disregards the decisions of our predecessor courts and of this court. This court was created to remove patent law questions from the regional circuit courts. *See* H.R. Rep. 96-1300, at 20 (1980) ("Directing patent appeals to the new court will have the beneficial effect of removing these unusually complex, technically difficult, and time-consuming cases from the dockets of the regional courts of appeals. . . . [T]he central purpose is to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in the administration of patent law."); *see also Federal Courts Improvement Act of 1979: Hearings Before the Subcomm. on Improvements in Judicial Machinery of the Comm. on the Judiciary, U.S. Senate*, 96th Cong. 197 (1979) (statement of Hon. Henry J. Friendly) ("What is needed is a group of judges, some but not all patent lawyers, with scientific training and interest, aided both by law clerks of similar bent and by a staff of experts in a variety of technologies, such as the Court of Customs and Patent Appeals has had for years and the courts of appeals in the very nature of things, cannot . . . "). To cite two regional circuit decisions, while jettisoning the precedents of the court

In *Hide-Ite Leather Co. v. Fiber Products Co.*, 226 F. 34 (1st Cir. 1915), the appeal was of two process claims for making leatherboard, and a product claim for leatherboard "made from pulp" and reciting the second step in the process claims plus the reference "substantially as described." The accused infringer did not use the same first step of the process. The court found that the invention was for a process, not a product, and therefore that the product claim was not infringed.

My colleagues also cite *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 876 (3d Cir. 1977), in which the court used the specification to resolve an ambiguity in the language of a product claim relating to "replica wooden beams" made of foamed urethane. The court reviewed whether ambiguous claim language required a closed or open mold, for this determined the question of anticipation based on a prior art reference that used an open mold. Thus the court stated that the manufacturing process described in the specification was "of paramount importance," and construed the claim in light of that process as requiring a closed mold, thus preserving the claim's validity as against the prior art that used and open mold. The sentence quoted by my colleagues out of its context, does not relate to the *en banc* court's new rule concerning process terms in product claims, and the *Paeco* case raised no question of whether the product was capable of description apart from the process.

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uniquely qualified to address patent questions and selected to supplant the regional circuits, is puzzling.

In addition to these two cases inaptly cited by the *en banc* court, other regional circuit decisions also contradict this court's new thesis. In *Dunn Wire-Cut Lug Brick Co. v. Toronto Fire Clay Co.*, 259 F. 258 (6th Cir. 1919), the court stated: "Certain it is, in view of the weight of authority and the latest decisions, that the inventor of a new and useful product or article of manufacture may have a patent which covers it and gives a monopoly upon it regardless of great variations in the method of making." *Id.* at 261.

In *Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274 (2d Cir. 1935) (L. Hand, J.), the court held invalid a product claim for a kind of "blind stitch" used in sewing, because the invention lay only in the process of producing the stitch, which itself "was not new." *Id.* at 279. While the stitch had not been claimed as the product of a particular machine or process, the court remarked on the conceivability of patenting such a product "merely as the product of a machine or process, even though it were anticipated if made in other ways," *id.*, observing that such a claim might serve a useful purpose in protecting against products that were produced by the same machine or process abroad and then imported. Of such a claim, wherein the product itself was anticipated but the process was new, the court stated "it would in that case not be infringed by anything but the product of the . . . process." *Id.* This routine statement of established law does not mean that when the product is itself new and useful and unobvious, it cannot be claimed as a product but must be tied to the machine that made it.

Judge Hand emphasized that this example related only to situations where the product itself was not new. The opinion explained that to be claimed as a product, the product "must be new as such, that is, regardless of the process or machine which makes it; and it must stand upon its own invention, again independently of the machine or process which makes it." *Id.* This was also the CCPA's view of product claims, providing the precedent carried forward to, and binding upon the Federal Circuit.[5]

III. THE *EN BANC* RULING

Defying precedent, the *en banc* court adopts for all situations "the basic rule that the process terms limit product-by-process claims," maj. op. at 17, whether the product is novel or known, and whether or not the new product could not have been fully described by its structure alone. The court eliminates the long-accepted expedient for new products whose structure is not fully known. While the *Scripps* deci-

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[5] There has been extensive commentary on this class of claim. *See, e.g.*, Jon S. Saxe & Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. Pat. Off. Soc'y 528, 559 (1960) ("Except in the chemical arts, a claim to a product must be in terms of the product's objective physical and chemical characteristics; but where these are unknown or impossible to express, a claim may define a product in terms of the process by which it is made. This product-by-process exception is to be distinguished from the use of process terminology as descriptive of a state of being."); Brian S. Tomko, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-by-Process Patents*, 60 Brook. L. Rev. 1693, 1696 (1995) (the *Atlantic* decision "pared the scope of a product-by-process patent to that of a glorified process patent").

sion is the only decision that is mentioned as "expressly overruled," maj. op. at 17, *Scripps* is only one of many cases now discarded.

The *en banc* majority's response to the dissenters is to state that "the inventor is absolutely free to use process steps to define this product" if its "structure is either not fully known or too complex to analyze," maj. op. at 19, but to eliminate the premise that the inventor thereby obtains a product claim, not a process claim. According to the majority, a patentee can continue to obtain product claims using process descriptors, but such product claims are treated as process claims for infringement. The applicant would still have to demonstrate patentability of the new product as a product (independent of the process), while enforcement of the patent against an identical product would be limited to the infringer's use of the process steps used as a descriptor. For the first time, claims are construed differently for validity and for infringement.

It has been an inviolate rule that patent claims are construed the same way for validity and for infringement. *See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement."); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1363 (Fed. Cir. 1998) ("Claims must be interpreted the same way for determining infringement

as was done to sustain their validity."); *Southwall Technologies, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."); *Beachcombers, International, Inc. v. WildeWood Creative Products, Inc.*, 31 F.3d 1154, 1163 (Fed. Cir. 1994) ("We have already interpreted the claims for purposes of assessing their validity. The same claim interpretation of course applies to the infringement analysis."); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("claims must be construed the same way for validity and for infringement"); *Smithkline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 882 (Fed. Cir. 1988) ("The claims of the '970 patent measure the invention at issue; thus, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); *see also* 5A *Chisum on Patents §18.01* (2007) ("A fundamental tenet of patent law is that a claim must be interpreted consistently for purposes of infringement and validity."); *id.* §18.03[2][h] (collecting cases).

As interpreted for validity, the claims obtained under the expedient of necessity are product claims, and are subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made. My colleagues hold that these are product claims for validity, but process claims for infringement. Departure from the rule that forbids such deviation requires sound reason, and fuller exploration

than the cursory brush-off dispensed by my colleagues.

I do agree with my colleagues that their logic is "simple." Maj. op. at 19. However, today's inventions are not simple. The needs of inventions of the past and present, and more so the future, are not simple. The public interest in invention and development of today's complex sciences, is not simple. The *en banc* court's "simple" hypothetical about "compound X, obtained by process Y," is simply irrelevant to the issues we must resolve. Scientists know that it is often easier to show that two products are the same, than to decipher their chemical or biological structure; for example, in the case at bar, comparing the X-ray diffraction patterns and absorption spectra could show that the products are the same, although their exact crystal structure is undefined. However, my colleagues announce that the only way to establish whether the accused compound is the same as the patented compound is by inquiring whether they were prepared by the same method. Maj. op. at 19-20 ("[W]hat analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes?"). That question has many answers, now stated to be irrelevant.

While the section of this opinion decided by the *en banc* court is largely directed to its reversal of precedent, the implementation of its ruling remains with the original panel. The panel decision enlarges the *en banc* ruling, further binding this court. The claims at issue state processes by which the new crystal form is "obtainable," although the specifica-

tion states that other methods might be used. The panel rules that a claim "cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims." maj. op. at 21, finding authority in *BASF*, which I have discussed *ante*. My colleagues thus continue to misapply the Court's ruling in *BASF*, where the Court stated repeatedly that the product in that case was a known product. *BASF*, 111 U.S. at 311 ("It was an old article."). In *BASF* the Court responded to the patentee's argument that it was entitled to cover all artificial alizarine made by any process, by observing that the patentee had not shown how the infringing and patented products "can be recognized," *id.* at 310, an aspect at the opposite pole from the case at bar, where the patentee provided elaborate details as to how the patented and accused crystal forms can be recognized.

The panel also states that "the applicant's statement in the file wrapper that 'the method of preparation . . . is not considered the heart of the present invention' should not be afforded undue gravitas." Maj. op. at 22. This too is an aberration of precedent, and is contrary to the many rulings of the Supreme Court and this court that afford due gravitas to the applicant's statement of what has been invented. *See, e.g., BASF*, 111 U.S. at 308 ("It is very plain that the specification of the original patent, No. 95,465, states the invention to be a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent . . . ."); *Plummer v. Sargent*, 120 U.S. at 443

(quoting specification of companion patent, where inventor stated "My invention consists in a process of covering iron with a very thin coating of oil, and then subjecting it to heat, the effect of which is to leave upon the iron a firm film, which is very durable, and gives the iron a highly ornamental appearance, like that of bronze"). The Federal Circuit's emphasis on the importance of the specification has been repeatedly stated. *E.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*) ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." (internal quotation marks omitted)).

The *en banc* court appears to misjudge the implications of its ruling, for the court states that it is now making available to "others the right to freely practice process Z [a different process] that may produce a better product in a better way." Maj. op. at 20. If others can indeed make a better product, this expedient presents no impediment. That is not the issue of this case. The issue is the right to make the same product, by making a process change that does not change the product. By now assuring that right, the exclusionary value of the claim to a new product is lost.

The purpose of the rule of necessity is to allow inventors of complex new products to obtain the patent scope to which their invention is entitled--the scope of the novel product they invented, no more and no less. The majority's change of law simply imposes unfairness as well as legal error on patent-supported advances.

SUMMARY

Precedent establishes that the correct construction of claims that recite process steps depends, like all claim construction, on what has been invented. No single rule fits all inventions. The construer must view the claims in light of the description of the invention in the specification, the prior art, and the prosecution history. In the complex law and practice of patents and inventions, the special expedient here of concern arises when the precise structure of a new product is not known from the information available when the patent application was filed. The law has enabled and endorsed this expedient of describing a product in order to claim it as a product, whereby validity and infringement are determined as a product, independent of any process term that was used to aid in defining the product. This expedient does not enlarge patent scope; it simply permits patenting what has been invented. A narrow but clear body of law has evolved to accommodate this need of complex technologies. This entire body of law is today overturned, *sua sponte* and without a hearing, without any participation of those affected, without identification of the intended benefits. I respectfully dissent from the *en banc* court's rulings, as well as the procedure by which they were reached.

LOURIE, *Circuit Judge*, dissenting from en banc Section III. A. 2.

I respectfully dissent from the court's en banc holding in Section III. A. 2 that product-by-process claims always require use of the recited process in order to be infringed.

I agree that there is substantial Supreme Court precedent that holds that product-by-process claims require use of the recited process for there to be infringement. However, many of those cases applied overly broad language to fact situations involving old products or used vague language that makes it difficult to determine whether the products were old or new. Clearly, however, when a product is old, a product-by-process claim cannot be interpreted as a claim to the product made by any means. The product is old and unpatentable per se. *BASF* in fact involved an old product. *See Cochrane v. Badische Anilin & Soda Fabrik,* 111 U.S. 293, 311, 4 S. Ct. 455, 28 L. Ed. 433, 1884 Dec. Comm'r Pat. 230 (1884) ("It was an old article.").

There is arguably a different situation that should apply to chemical-biological products today than to mechanical products of more than a century ago. When a product is new and the inventor claims it by a process of preparation, I fail to see why the product-by-process claim should not be interpreted as a product claim that can be infringed even when the product is made by means other than that recited in the claim. Supreme Court precedent dealing with old products, while utilizing broad language, does not foreclose that possibility. The Court years ago did not have occasion to consider today's innovations or decide whether a distinction should be made between a new chemical-biological product and an old product made by a new process.

And there may be differing results depending upon the exact wording of a claim at issue. For example, a claim reading "when made by" might only be infringed when the recited process is used by the

accused, as it is situational. On the other hand, a claim reading "obtainable by" refers to capability, so it might not require use of the process to infringe. "Obtained by" is ambiguous. Bright lines have their uses, but judging should take account of differing circumstances. In addition, of course, in order to sustain any claim for infringement, a patent owner must prove that an accused product is the same as that covered by an asserted claim. If the reason a product was claimed by its process was that its structure was unknown, then, if, at the time infringement is asserted, there still is no means to ascertain structurally whether the accused product is the same as that claimed, the infringement claim fails. However, that should not mean that a new product claimed by a process of preparation cannot ever be infringed when made by another process.

It may be that with today's analytical techniques there is little need for product-by-process claims. After all, claim 1 of the Abbott patent is a claim to a compound, not only by name, but also by certain of its characteristics. A claim to a product defined by its characteristics or properties surely is a proper claim.

However, product-by-process issues still seem to come before us and I would make a distinction between old products and new products in interpreting product-by-process claims. Accordingly, I respectfully dissent from the court's en banc holding.

LUPIN LIMITED, Plaintiff, v. ABBOTT LABORATORIES, and ASTELLAS PHARMA, INC., Defendants.

ABBOTT LABORATORIES, and ASTELLAS PHARMA, INC.,
Counterclaim Plaintiffs,
v.
LUPIN LIMITED, AND LUPIN PHARMACEUTICALS, INC.,
Counterclaim Defendants.

Civil Action No. 3:06cv400

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA, RICHMOND DIVISION

491 F. Supp. 2d 563

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June 14, 2007, Filed

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JUDGES: Robert E. Payne, Senior United States District Judge.

OPINION BY: Robert E. Payne

OPINION

MEMORANDUM OPINION

This matter is before the Court on Plaintiff's Motion for Summary Judgment on Noninfringement and Invalidity for U.S. Patent No. 4,935,507 (Docket No. 208). For the reasons set forth below, the motion is granted in part and denied in part.

BACKGROUND

This action involves U.S. Patent No. 4,935,507 ("'507 patent"), which covers Crystal A, a particular form of the antibiotic cefdinir. (See Docket No. 188, Mem. Op. at 23.) Astellas Pharma, Inc. ("Astellas") obtained the '507 patent in 1990, five years after it had obtained U.S. Patent No. 4,559,334 ("'334 patent"), which also covered forms of cefdinir. The *'334 patent* expired on May 6, 2007, and the '507 patent is set to expire on December 4, 2011.[1]

Because the '334 patent expired on May 6, 2007, Astellas can no longer prevent competitors from producing forms of cefdinir not covered by the '507 patent, which is limited in scope to Crystal A. Abbott Laboratories ("Abbott") holds a license from Astellas to practice the '507 patent. Pursuant to that license, Abbott makes and markets Crystal A in a branded cefdinir product called Omnicef(R), which currently has annual sales exceeding $ 600 million. Seizing on the expiration of the '334 patent, Lupin Limited ("Lupin") is now marketing a generic form of cefdinir to compete with Omnicef(R), and seeks a declaration that its product "has not infringed, does not infringe, and will not infringe any valid and enforceable claim of" the '507 patent. (Compl. for Declaratory J. at 1.) Abbott and Astellas have each filed counterclaims

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[1] Astellas received a patent term extension (PTE) for the '507 patent on January 19, 2001. Without that PTE, the '507 patent would expire on August 8, 2008. Whether the '507 patent's PTE is enforceable is disputed by the parties, but the parties have agreed to dismiss this claim in a Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349).

against Lupin, alleging infringement of the '507 patent. (Dockets No. 18 and 21.)

Lupin seeks summary judgment on six independent grounds: (1) non-infringement of Claims 1-5 of the *'507 patent*, both literally and under the doctrine of equivalents; (2) invalidity of the '507 patent for obviousness; (3) invalidity of the 507 patent for anticipation; (4) invalidity of the '507 patent for improper inventorship; (5) invalidity of the '507 patent for lack of enablement; (6) the absence of legal or equitable remedy for trace infringement. (See Lupin Limited's Mem. of Law in Supp. of Mot. for Summ. J. of Noninfringement and Invalidity for U.S. Patent No. 4,935,507 and Supplemental Declaration of Amy D. Brody ("Lupin Mem.").) Abbott and Astellas oppose Lupin's motion, and contend that summary judgment is inappropriate on any of those bases. (See Abbott Laboratories' and Astellas Pharma, Inc.'s Mem. in Resp. to Lupin's Mot. for Summ. J. ("Abbott and Astellas Mem.").) Oral argument was heard on May 21, 2007 and, for the reasons that follow, the Court now grants Lupin's summary judgment motion with respect to the literal infringement of Claims 2-5 and the infringement of all claims under the doctrine of equivalents.

DISCUSSION

Summary judgment is appropriate in a patent case, as in other cases, when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Nike Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994). When analyzing a summary judgment motion, the facts must be con-

strued in the light most favorable to the non-movant, and all reasonable inferences must be drawn in the non-movant's favor. See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986).

A. Infringement

A determination of infringement requires a two-step, claim-by-claim analysis. See *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001). First, the court must properly construe the claim; second, "the claim as properly construed must be compared to the accused device or process." *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001). An infringement issue is properly decided upon summary judgment when no reasonable jury could find, by a preponderance of the evidence, that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents. Id.

1. Literal Infringement of Claim 1

After oral argument, the Court concluded that there were genuinely disputed issues of material fact which precluded an award of summary judgment on the literal infringement of Claim 1. In a Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349), the parties have agreed to dismiss without prejudice any claims related to the literal infringement of Claim 1. Because that issue has been resolved thusly by the parties, it is not necessary to address it further.

2. Literal Infringement of Claims 2-5

Claims 2-5 are product-by-process claims. (See Docket No. 188, Mem. Op. at 39.) In an order dated May 10, 2007 (Docket No. 234), the Court informed the parties that the Federal Circuit's decision in *Atlantic Thermoplastics Co., Inc. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992) would govern the literal infringement analysis of Claims 2-5. That order was necessary because the parties disagree about whether the product-by-process infringement analysis should be controlled by *Atlantic Thermoplastics or Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Scripps and *Atlantic Thermoplastics* announce conflicting rules respecting the proper analysis of product-by-process claims in an infringement action. In *Scripps*, a panel of the Federal Circuit determined that "the correct reading of the product-by-process claims is that they are not limited to product prepared by the process set forth in the claims." 927 F.2d at 1583. One year later, the decision in *Atlantic Thermoplastics* held that "process terms in product-by-process claims serve as limitations in determining infringement." 970 F.2d at 846-47. As district courts have long acknowledged, those two holdings are at odds with one another. See, e.g., *Trustees of Columbia Univ. v. Roche Diagnostics GmbH*, 126 F. Supp. 2d 16, 31 (D. Mass. 2000).

Scripps and *Atlantic Thermoplastics* are different in substance as well as in result. While *Scripps* enunciated its rule without legal citation or significant analysis, see 927 F.2d at 1583, the *Atlantic Thermoplastics* decision reached its contrary conclu-

sion only after thoroughly examining both the history of product-by-process claims and the relevant precedent from the Supreme Court of the United States and the Federal Circuit pertaining to the infringement of such claims, see id. at 838-47. Indeed, the *Scripps* analysis was so brief by comparison that the *Atlantic Thermoplastics* court determined that *Scripps* would have been decided differently had Supreme Court precedent and other relevant authority been considered. *See* 970 F.3d at 838 n.2.

Notwithstanding the analytical parsimony in *Scripps*, some district courts have decided to follow *Scripps* because it was issued first and has not been overruled en banc. See, e.g., *Trustees of Columbia Univ.*, 126 F. Supp. 2d at 32. On the other hand, other district courts have concluded that *Atlantic Thermoplastics* constitutes a proper statement of the law, and, therefore, should govern the analysis of product-by-process claims. See, e.g., *Tropix, Inc. v. Lumigen, Inc.*, 825 F. Supp. 7, 8-10 (D. Mass. 1993). Abbott and Astellas urge the Court to adopt *Scripps*, which offers a broader reading of product-by-process claims, while Lupin urges application of *Atlantic Thermoplastics*.

Having considered the matter further, the Court concludes, as it did in its order of May 10, 2007, that *Atlantic Thermoplastics* must control the product-by-process analysis because it, not *Scripps*, reflects controlling Supreme Court precedent. At oral argument on the motion for summary judgment, Abbott and Astellas disputed the Federal Circuit's interpretation of Supreme Court precedent in *Atlantic Thermoplastics*. (See Summ. J. Hr'g Tr. 185-89.) Having considered that argument, the Court finds no

basis for concluding that the decision in Atlantics Thermoplastics either misconstrued or misapplied the controlling decisions of the Supreme Court. Moreover, a district court is not at liberty to ignore relevant and controlling Supreme Court precedent simply because it was not considered in an appellate decision addressed to the same subject as the Supreme Court's antecedent decisions. Thus, because *Atlantic Thermoplastics* reflects the relevant and controlling Supreme Court precedent, and *Scripps* does not, the process terms in Claims 2-5 must "serve as limitations in determining infringement." 970 F.2d at 846-47.

Under the rule set forth in *Atlantic Thermoplastics*, Lupin's product cannot literally infringe any of Claims 2-5 unless it is made using each of the process limitations set forth in one of those claims. Abbott and Astellas have presented no evidence that Lupin is practicing the process steps set forth in Claims 2-5. Indeed, Abbott and Astellas have conceded that literal infringement of Claims 2-5 cannot be established if the product-by-process analysis is performed pursuant to the rule in *Atlantic Thermoplastics*. Therefore, Lupin's motion for summary judgment is granted with respect to the literal infringement of those claims.

3. Doctrine of Equivalents

If Lupin's product does not literally infringe Claims 1-5, it may still infringe under the doctrine of equivalents if there is "equivalence between those elements of the accused product and the claimed limitations of the patent invention that are not literally infringed." *Zelinski v. Brunswick Corp.*, 185

F.3d 1311, 1316 (Fed. Cir. 1999). The test of equivalency is directed to the individual claim limitations, and not to the invention itself. As the Supreme Court explained in *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*: "Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." 520 U.S. 17, 29, 117 S. Ct. 1040, 137 L. Ed. 2d 146 (1997).

An element in the accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to one of ordinary skill in the art. *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1331-32 (Fed. Cir. 2001). A difference may be "insubstantial" if the accused product's element "performs substantially the same function in substantially the same way to obtain the same result as the claim limitation." *Eagle Comtronics, Inc. v. Arrow Commun. Labs., Inc*, 305 F.3d 1303, 1315 (Fed. Cir. 2002) (citation and internal quotations omitted). Under no circumstances, however, is this element-focused equivalency inquiry "allowed such broad play as to effectively eliminate [any] element in its entirety." *Warner-Jenkinson*, 520 U.S. at 29.

Notwithstanding the foregoing well-established, element-focused dispositive principles, Abbott and Astellas contend that Lupin's product infringes Claims 1-5 "because Lupin's product performs substantially the same function, in substantially the same way, to produce substantially the same result as the claimed crystalline cefdinir." (Abbott and Astellas Mem. at 12 (emphasis added).) Abbott and

Astellas focus, in particular, on the "bioequivalence" and "stability and solubility" similarities between Lupin's product and Crystal A. (Id. at 12-13.) Even if Abbott and Astellas are correct about the functioning of Lupin's product, no reasonable jury could conclude, based on a product-focused analysis, that Lupin's product contains elements insubstantially different from each and every limitation in one of Claims 1-5 (which focus on peak positions and process steps, not stability, solubility, or other characteristics associated with Crystal A as a whole). See *Schoell v. Regal Marine Indus., Inc.*, 247 F.3d 1202, 1210 (Fed. Cir. 2001) (noting that similarities between products as a whole do not, by themselves, allow inferences respecting the equivalence of individual elements and claim limitations). To the extent that Abbott and Astellas rely on characteristics of Lupin's product unrelated to the individual limitations set forth in Claims 1-5, their doctrine of equivalents theory is without merit.

However, Abbott and Astellas make three arguments which, at least, loosely relate to the individual limitations contained in Claims 1-4.[2] First, Abbott and Astellas claim that "the peak positions in Lupin's products are at most insubstantially different from the positions of the peaks claimed in the patent." (Abbott and Astellas Mem. at 14.) They base

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[2] Abbott and Astellas make no element-focused contentions with respect to Claim 5. (See Abbott and Astellas Mem. at 14-15.) That being the case, summary judgment is appropriate for noninfringement of Claim 5 under the doctrine of equivalents notwithstanding the merits of any element-focused arguments made by Abbott and Astellas with respect to Claims 1-4.

that argument entirely on a single paragraph in Dr. Atwood's first expert report. (*See id.*) In paragraph 50 of that report, Dr. Atwood states the following:

> Even a crystal of cefdinir with 6.0 - 7.5% w/w water in the lattice would contain the peaks recited in claim 1 of the '507 patent, but they would at most be insubstantially shifted by virtue of the expansion of the crystal lattice along the c direction upon the insertion of additional water molecules. In every material respect, crystalline cefdinir monohydrate and crystalline cefdinir hydrate containing 6.0-7.5% w/w water are substantially the same as each other.

(First Expert Report of Jerry L. Atwood P 50.) Under the doctrine of equivalents, this paragraph alone is insufficient to allow a reasonable jury to conclude by a preponderance of the evidence that Lupin's product infringes Claim 1. First, Dr. Atwood makes no mention whatsoever of Lupin's particular product. Instead, he offers a theoretical discussion comparing abstract hydrated forms of crystalline cefdinir that might share characteristics with Lupin's product. Second, Dr. Atwood does not conduct an element-by-element analysis of Claim 1 as compared to Lupin's product. For example, he does not say which particular peak in Lupin's product corresponds with the peak that must exist at about 14.7 and why the difference between the two peak positions is "insub-

stantial" to a person of ordinary skill in the art.[3] Thus, while Dr. Atwood's statements relate to the individual limitations in Claim 1 (the existence and position of peaks), he nevertheless "has not opined in a sufficient manner regarding infringement under the doctrine of equivalents." *Microstrategy, Inc. v. Business Objects, S.A.*, 331 F. Supp. 2d 432, 445 (E.D. Va. 2004). Without more, Dr. Atwood's conclusory and abstract opinion is simply insufficient to support a finding of infringement under the doctrine of equivalents with respect to Claim 1. *See* Schoell, 247 F.3d at 1210 ("The doctrine of equivalents is not a talisman that entitles a patentee to a jury trial on the basis of suspicion; it is a limited remedy available in special circumstances, the evidence for which is the responsibility of the proponent.")

Second, Abbott and Astellas contend that, even if Lupin's product does not show "peaks" at about 14.7 or about 22.0, it does show "increases in intensity" at those angles. (Abbott and Astellas Mem. at 14.) Abbott and Astellas again invoke Dr. Atwood to argue that those increases in intensity are insubstantially different from peaks. (Id.) However, Dr. Atwood's third declaration, on which Abbott and Astellas rely for this argument, does not equate "peaks" with mere increases in intensity. (*See id.* Ex. 9 PP 9-11.) For example, paragraph 9 of Dr. Atwood's third declaration depicts features which he labels "peaks," but, while those "peaks" take slightly different

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[3] Moreover, Dr. Atwood's conclusory opinion does not enable the Court to determine whether his theory of equivalence would "entirely vitiate" a particular claim element or otherwise render the peak limitations in Claim 1 impermissibly meaningless. *Warner-Jenkinson*, 520 U.S. at 39 n.8.

forms, each increase in intensity labeled a "peak" has an apex surrounded by a lower intensity measurement on each side. (Id. P 9.) While paragraphs 10 and 11 of the declaration do discuss the possibility that peaks may overlap, or that a peak may protrude as a "shoulder" from another peak, nothing in paragraphs 10 and 11 indicates that a peak, of any shape or size, may be anything other than an apex immediately preceded by and immediately followed by a lower intensity measurement. (*See id.* PP 10-11.) Therefore, Dr. Atwood's third declaration does not support Abbott's and Astellas' contention that mere "increases in intensity" are insubstantially different from peaks.

Even if Dr. Atwood's third declaration did support that argument, Dr. Atwood does not point out, on an element-by-element basis, which "increases in intensity" in Lupin's product correspond to the peaks required by Claim 1.[4] The failure to offer proof on that subject is fatal at this stage.

Third, and finally, Abbott and Astellas argue that Lupin's product infringes Claims 2-4 by equivalents because the processes described by Claims 2-4 may result in both Lupin's product and the crystalline cefdinir covered by the '507 patent. (See Abbott and Astellas Mem. at 15.) Therefore, Abbott and Astellas argue, "any difference between the two crystal forms is insubstantial." (*Id.*) Again, however, this argument improperly focuses on completed products and

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[4] Nor do Abbott and Astellas explain why the claim limitations in Claim 1 would not be rendered totally and impermissibly meaningless if mere "increases in intensity" could serve as infringing equivalents.

not on *Lupin's process steps*, which are the elements at issue here. In order to demonstrate infringement by equivalents, Abbott and Astellas must offer proof to show why *Lupin's processes* feature a step that is insubstantially different from each process limitation set forth in one of Claims 2-4. Abbott and Astellas offer no such proof. They certainly do not explain why *Lupin's processes* are insubstantially different from each process step described in one of Claims 2-4 simply because the processes in Claims 2-4 might produce Lupin's product (among others). Because Abbott's and Astellas' equivalency analysis with respect to Claims 2-4 fails to address the pertinent process steps - Lupin's-summary judgment for Lupin is required.

In sum, Abbott and Astellas largely make irrelevant product-focused arguments under the doctrine of equivalents, and, where their arguments do properly focus on individual claim elements, they do not offer supporting evidence sufficient to defeat Lupin's motion for summary judgment. Accordingly, summary judgment for Lupin is required with respect to the infringement of Claims 1-5 under the doctrine of equivalents.

B. Validity and Availability of Legal Remedies

After oral argument on the motion for summary judgment, the Court concluded that the existence of genuinely disputed material facts precluded summary judgment on Lupin's contentions respecting invalidity and the availability of remedies. In the Stipulated Order of Dismissal dated June 6, 2007 (Docket No. 349), the parties agreed to dismiss without prejudice any claims related to invalidity. Be-

cause those issues have been resolved by the parties, it is not necessary to address them further. In addition, because the issues related to infringement have been dismissed or resolved in favor of Lupin, the Court need not consider the availability of legal remedies to Abbott and Astellas.

CONCLUSION

For the reasons set forth above, Lupin's motion for summary judgment is granted with respect to the literal infringement of Claims 2-5 and infringement of all claims under the doctrine of equivalents. Lupin's motion is otherwise denied.

The Clerk of the Court is directed to send a copy of this Memorandum Opinion to all counsel of record.

It is so ORDERED.

Robert E. Payne

Senior United States District Judge

Date: June 14, 2007

Richmond, Virginia